# **SIEMENS**

# SONOLINE G20 Ultrasound Imaging System [1] Instructions for Use

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# SONOLINE G20 Ultrasound Imaging System [1] Instructions for Use

#### Software Versions 1 and 2

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#### **CE Declaration**

This product is provided with a CE marking in accordance with the regulations stated in Council Directive 93/42/EEC of June 14, 1993 concerning Medical Devices. Siemens Medical Solutions USA, Inc., is certified by Notified Body 0123 to Annex II.3 – Full Quality System.

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# **About This Manual**

The Instructions for Use consists of two volumes:

• [1] Instructions for Use

The [1] Instructions for Use includes both a general overview and a technical description of the ultrasound imaging system. This manual contains detailed information on the safety and care of the ultrasound system and its transducers. A chapter is dedicated to the description of all system controls. The [1] Instructions for Use also includes the procedures for system setup and beginning an exam.

• [2] Instructions for Use

The [2] Instructions for Use includes procedures for acquiring and optimizing images. This manual provides procedures for general and exam-specific measurements and calculations.

The *System Reference* provides reference information for the ultrasound imaging system.

#### **Conventions**

Conventions used throughout this manual are listed below. Take a moment to familiarize yourself with these conventions.

#### **Cross-References**

This manual provides you information by topic. When additional information exists within this or other manuals, a reference graphic and the name of the book is provided in the right column. If the information exists within the chapter, a cross-reference to the page number is listed. Otherwise, information is referenced by chapter number.

# [1] Instructions for Use

Screen Saver Ch 1 Intended Use Ch 1

#### [2] Instructions for Use

Imaging Functions ChA1

## **System Presets**

You can use the options and settings available in the system presets menu to set up the ultrasound system with your preferences. Presets define the configuration of the system software whenever you power on the system.

A complete listing of system presets is located in the *System Reference*. Whenever a system preset is discussed in other chapters or in the User and Reference Manuals, a graphic is provided in the right column.

The graphic identifies a preset option or setting in the system presets menu that is available for you to customize your ultrasound system. The name of the category on the menu containing the system preset is listed for your convenience.

#### **System Reference**

Accessories and Options Ch 2 Storage 1-4



#### F6

Default Settings
► Automatic Freeze
Response

# Warnings, Cautions, and Notes

MARNING: Warnings are intended to alert you to the importance of following the correct operating procedures where risk of injury to the patient or system user exists.

⚠ **Caution:** Cautions are intended to alert you to the importance of following correct operating procedures to prevent the risk of damage to the system.

Note: Notes contain information concerning the proper use of the system and/or correct execution of a procedure.

# **Control Panel Keys, Controls, and Menu Selections**

Keys and controls located on the control panel are identified by uppercase, boldface type.

Example: Rotate the **DEPTH/ZOOM** control.

Function keys located on the keyboard are identified by the number of the function key.

Example: Press the F6 key.

Menu selections are indicated with the name of the selection in boldface type.

Example: Select **Next** to access the second page of on-screen

menu selections.

## **Selection of On-Screen Objects**

The **SET** key on the control panel functions as a point-and-select device (similar to a computer mouse) when used with the trackball. To select an on-screen object such as a button or a ▼ symbol, roll the trackball to position the pointer (cursor) on the object and then press the **SET** key on the control panel.

In this manual, the term "select" or "click" describe the trackball and **SET** key action required to select an on-screen object. In the example below, phrases A, B, C, and D are equivalent actions.

- A. Roll the trackball to the **Search** button and then press the **SET** key.
- B. Select the **Search** button.
- C. Click the **Search** button.
- D. Click Search.

## **Special Terms and Menu Options**

Special terms are indicated in boldface italics and are accompanied by a brief description on their first use in the manual.

Example: Provides on-screen anatomical graphics of **pictograms** that indicate the anatomy under evaluation.

Within a procedure, options in the system presets are identified in text as boldface type.

Example: Highlight the **Keyboard – Annotation** option.

# **Table of Contents**

# **Instructions for Use**

Chapter Title Chapter Description				
Chapter 1 Introduction	General overview of the diagnostic ultrasound imaging system, including system options, features, and design.			
Chapter 2 Safety and Care	Detailed information on system safety and how to care for and maintain the system, transducers, and transducer accessories.			
Chapter 3 System Controls	Explanation of all controls and keys on the control panel, alphanumeric keyboard, and optional footswitch.			
Chapter 4 System Setup	Detailed descriptions of how to transport, set up, and prepare the system for use, including transducer connection and system startup procedures.			
Chapter 5 Beginning an Examination	Information on starting an examination, including instructions for entering and editing patient data and selecting an exam type, imaging mode, and transducer.			
Chapter 6 Technical Description	Technical description of the ultrasound system.			

**Note:** Not all features and options described in this publication are available to all users. Please check with your Siemens representative to determine the current availability of features and options.

# 1 Introduction

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# **System Overview**

The SONOLINE G20™ system is a portable, digital diagnostic ultrasound imaging system. The system utilizes advanced imaging processing and transducer technology. The operating system is based on Windows® technology.

The system software supports 2D-mode and M-mode imaging, standard applications, exam-specific imaging presets, measurements, pictograms, annotations, reports, worksheets, and system diagnostics. The system is equipped with a DIMAQ-IP integrated workstation, including a CD-R/W drive. The workstation provides capabilities for digital acquisition, storage, and review of ultrasound studies. Additional system options provide integration into a networking environment.

The design of this compact and lightweight system allows you access to exam sites where floor space is limited. The ultrasound system can navigate doorways, elevators, mobile van doors, and small examination rooms such as those in clinics, in doctor's offices, and in emergency departments.

# **Configurations**

System configurations:

- Two standard array transducer ports
- Two standard array transducer ports and one mechanical sector transducer port1
- Two standard array transducer ports and one parking port for linear and curved array transducers

# **Language Formats**

Operating system software and control panel overlays support English, German, French, Spanish, and Italian languages.

# **Transducers**

Wideband transducer technology supports MultiHertz™ multiple frequency imaging. Multi-frequency capability is available for all imaging transducers.

You can connect multiple transducers to the ultrasound imaging system, with one transducer being the active transducer.

[1] Instructions for Use

Technical Description Ch<sub>6</sub> Software/Hardware Options Ch 6

1 - 3

<sup>&</sup>lt;sup>1</sup> Requires software version 2.0 or higher

△ Caution: In the United States of America, federal law restricts this device to sale or use by, or on the order of, a physician.

The SONOLINE G20 ultrasound system supports the following applications:

- Abdominal
- Obstetrical
- Gynecological
- Endovaginal
- Urological
- Small Parts (Breast, Testicular, Thyroid)
- Musculoskeletal
- Orthopedic
- Cardiac
- Cranial
- Endorectal
- EM (Emergency Medicine)<sup>1</sup>

#### System Reference

Listing of
Transducers
and Intended
Application

Ch 1

<sup>&</sup>lt;sup>1</sup> Requires software version 2.0 or higher

# **Operating Modes**

**Important:** At the time of publication, A-mode was not cleared for use by the U.S. Food and Drug Administration. Before using A-mode, check the current regulations for the country in which you are using this system to determine if A-mode is cleared for use.

- A-mode: A-mode is the amplitude mode. It can be displayed in a 2D-mode image.
- **2D-mode:** 2D-mode is the default setting. When the system is powered on, the image screen displays in 2D-mode.
- **Split (B+B) mode:** Split mode creates side-by-side images from one 2D-mode image. The two images are simultaneously real-time or frozen.
- Dual-mode: Dual-mode displays two acquired 2D-mode images.
   Because the images are obtained separately, only one image at a time displays in real-time.
- **4B-mode**: 4B-mode displays four acquired 2D-mode images. One image at a time displays in real-time.
- **2D/M-mode:** 2D/M-mode displays a 2D image and an M-mode sweep.
- **Split 2D/M-mode:** Split 2D/M-mode displays simultaneous 2D-mode images with an M-mode sweep.
- M-mode: Full screen M-mode display is available.

# **Image Screen Layout**

The monitor on the ultrasound system displays clinical images together with important operating parameters and patient data. There is a variety of on-screen overlays and graphical objects to aid in image evaluation.

Many *fields* or areas of data displayed on the screen are multi-functional. The image field can display a 2D-mode image, M-mode sweep, and their combinations, sets of calipers, pictograms and annotation text, biopsy guidelines, and CINE icons. An image can be inverted on a vertical axis and reversed on a horizontal axis to facilitate viewing and measurements.

EMC Note: Operating the ultrasound imaging system in close proximity to sources of strong electromagnetic fields, such as radio transmitter stations or similar installations may lead to interference visible on the monitor screen. However, the device has been designed and tested to withstand such interference and will not be permanently damaged.

#### [2] Instructions for Use

Sample Image Screen

Ch A2

#### **System Reference**

System Presets

Ch 3

# **Screen Saver**

The screen saver feature automatically replaces the display with a blank screen after the system has been inactive for a specified number of minutes. Restore the screen display by pressing any key or adjusting any control. The first key that you press will restore the view without performing a function. Press the key again to execute the command.



#### F6

Display ► Screen Saver Display ► Screen Saver Type

Display

Screen Saver Time

# **Documentation and Storage Devices**

listed in the System Reference. Any use of other devices with the system is at the user's risk.

**System Reference** 

Accessories and Options

Ch 2

The system is configured with a CD (compact disk) disk drive for storage of system software, patient data, and images.

You can connect one on-board image/report documentation device to the system.

- Black and white video printer (standard equipment)
- Videocassette recorder (VCR)

Note: Refer to the manufacturer's instructions for specific information concerning the operation of these devices.



⚠ **WARNING:** Accessory equipment connected to the analog and digital interfaces must be certified according to the respective EN and IEC standards (for example, EN 60950 and IEC 60950 for data processing equipment and EN 60601-1 and IEC 60601-1 for medical equipment). Furthermore, all configurations shall comply with the system standards EN 60601-1-1 and IEC 60601-1-1. Anyone who connects additional equipment to any of the signal input or signal output ports configures a medical system and is therefore responsible that the system complies with the requirements of the system standards EN 60601-1-1 and IEC 60601-1-1. Siemens can only guarantee the performance and safety of the devices listed in the System Reference. If in doubt, consult Siemens service department or your local Siemens representative.

# **Measurements and Reports**

The measurement function is arranged by exam type and is available for use with all exam types. The ultrasound system has measurement and report packages for the following exam types:

- Obstetrics
- Early Obstetrics
- Gynecology
- Orthopedics
- Urology
- Cardiac
- EM (Emergency Medicine)<sup>1</sup>
- Rectal<sup>1</sup>

Additional specialty measurements include Hip Dysplasia, Residual Volume, and Thyroid Volume.

#### [2] Instructions for Use

Measurements	
and Reports:	
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Obstetrical	Ch B2
EM	Ch B3
Urology	Ch B4
Rectal	Ch B4
Cardiac	Ch B5
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<sup>&</sup>lt;sup>1</sup> Requires software version 2.0 or higher

# **User-Defined System Settings**

You can customize many features of the ultrasound system by using the system presets to designate default settings, or *presets*. The values are stored in non-volatile memory and will remain intact when the system is powered off.

Each user of the system can determine settings for imaging preferences and default settings, then store them on a disk. Those user-defined settings can then be loaded along with new system software. The disk also serves as a backup.

# QuickSets

The **QuickSet**<sup>TM</sup> feature allows you to capture an optimized configuration of imaging parameter settings for a combination of a specific transducer and exam.

# QuickSets Ch A

# ReadySet Feature

Use the ReadySet<sup>™</sup> onscreen workflow shortcut feature to provide immediate access to your most frequently-used functions.

For example, you can assign an onscreen button to the image rotation function. During imaging, you would roll the trackball to **Rotate** icon (button) and then press the **SET** key for each 90° rotation of the image.

Use the system presets to assign onscreen buttons to the functions to use with the ReadySet feature. For software versions 2.0 and higher, you can also use the system presets to select a display option for the ReadySet icons (onscreen buttons).

# System References System Presets Ch 3 F6 ReadySet

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# **Operating Safety and Environment**

Do not operate the ultrasound imaging system until you fully understand the safety considerations and procedures presented in this manual.

[1] Instructions for Use

System Controls Ch

# **System Symbols**

The table below is provided for your identification of important symbols located in labels on the ultrasound imaging system and transducers.

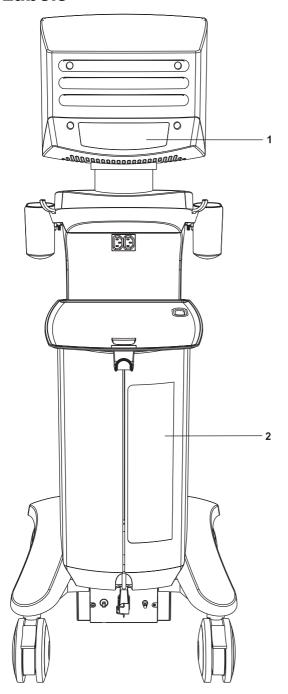
Symbol Explanation				
$\sim$	Alternating Current			
V~	AC (alternating current) voltage source			
Â	Caution: Risk of electric shock.			
- <b>1</b>	Type BF Defibrillator-proof Patient Connection			
★	Type BF Applied Part			
	Type CF Patient Connection			
<u> </u>	Consult Operator's Manual			
Ŭ.	Equipotential Connection			
2	Footswitch Connector			
	Headphone Connection			
N.	Degauss Control			
	Monitor self test			

Symbol	Explanation			
	Monitor Contrast control			
->	Monitor Brightness control			
<u></u>	Protective Earth Ground			
Ţ	Signal Earth Ground			
<b>⊕</b>	Signal Input			
$\bigcirc$	Signal Output			
	Video Connection (monochrome video signals)			
<u> </u>	Start (of action for equipment)			
	Digital Interface, RS-232-C connection			
Ψ	USB Connection			
***	Ethernet 10/100BaseT Connection			
- <u>Ö</u> -	Status Indicator for DC Power Good (Green) or Green Indicator Light			
0	Printer Connection			
	Electronic Array Transducer Port (for standard transducers)			
	Mechanical Sector Transducer Port (for mechanical sector transducers)			
	Parking Port (for linear and convex transducers)			
B ← → B	Transducer unlock (left) and lock (right) positions			

Symbol	Explanation
6	Unlocked position
8	Locked position
	Audio
	Audio Level
5 kg MAX 11 lbs MAX	Shelf Weight Restriction
	ON only for MAINS control
	OFF only for MAINS control
Ů	Power "On" standby switch
0	"ON" only for part of the equipment
Ċ	"OFF" only for part of the equipment
IPX8	Protected against the effects of continuous immersion in water
	Do not open. Refer servicing to qualified service personnel.
(A) P)	Danger: Risk of explosion if used in the presence of flammable anesthetics
<b>C E</b> 0123	Manufacturer's declaration of product compliance with applicable EEC directive(s) and the European notified body.
CE	Manufacturer's declaration of product compliance with applicable EEC directive(s).

Symbol	Explanation
D	DEMKO-Denmark approval mark.
c Sausus	UL symbol for listing as recognized components for Canada and United States of America
ДЕ 01	Gost-R symbol indicates that this product is certified for conformity to the safety requirements of Russian state standards.
	(Installierte Volumen Komponente)
IVK	Identifier of selected system components or parts for product traceability.
UL LISTED	UL Listing Mark
	Bar Code
6AM - 6P1 9V	9 Volt Battery
2003	Date of Manufacture symbol with the date below

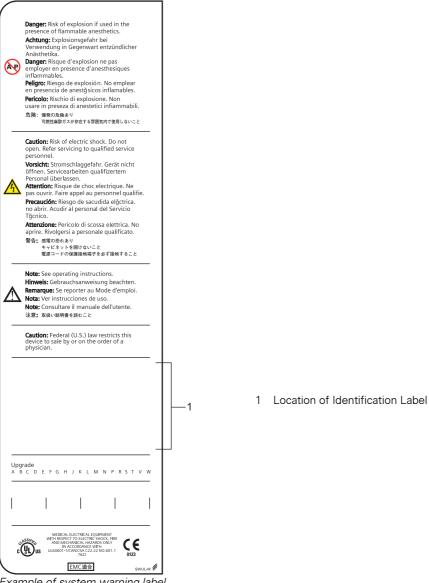
# Labels



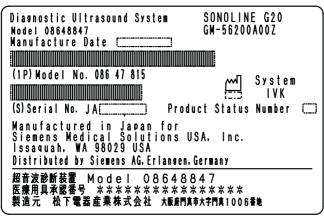
- 1 X-ray shielding notice
- 2 System warning label Identification label Certification label



Example of X-ray shielding notice: "X-ray emission complies with FDA (DHHS) radiation performance standards, 21 CFR subchapter J applicable at date of manufacture."



Example of system warning label.



Example of identification label.





Example of certification label – 115V, 230V.

Example of certification label – 230V.

MARNING: This equipment is not suitable for intracardiac use or direct cardiac contact.

⚠ **WARNING:** For neonatal head imaging, Siemens recommends that you exercise special care during neonatal cephalic scanning to avoid possible damage to the posterior region of the eye. The ultrasound energy emitted by the transducer easily penetrates the fontanels of the infant.

⚠ **WARNING:** Siemens makes every effort to manufacture safe and effective transducers. You must take all necessary precautions to eliminate the possibility of exposing patients, operators, or third parties to hazardous or infectious materials. These precautions should be considered in the use of any application that may indicate the need for such care, and during endocavity or intraoperative scanning; during biopsy or puncture procedures; or when scanning patients with open wounds.



⚠ **WARNING:** To eliminate the possibility of exposing patients, operators, or third parties to hazardous or infectious materials, always dispose hazardous or infectious materials according to medical regulations for biohazardous waste.

MARNING: There have been reports of severe allergic reactions to medical devices containing latex (natural rubber). Health care professionals are advised to identify latex-sensitive patients and to be prepared to treat allergic reactions promptly. For additional information in the U.S.A., refer to FDA Medical Alert MDA91-1.

⚠ **WARNING:** Ultrasound energy is transmitted more effectively through water than through tissue. When using a standoff device of any kind, for example, a gel pad, the actual mechanical and thermal indices, MI and/or TI, may be higher than indicated in the output display on the system.

[1] Instructions for Use

Transducer Care

The assessment of the biological effects of diagnostic ultrasound on humans is a subject of ongoing scientific research. This system, and all diagnostic ultrasound procedures, should be used for valid reasons, for the shortest possible period of time, and at the lowest mechanical and thermal indices necessary to produce clinically acceptable images.

According to the ALARA (As Low As Reasonably Achievable) principles, acoustic output should be set to the *lowest level required to satisfactorily perform the examination*.

The ultrasound imaging system complies with the standards of the American Institute of Ultrasound in Medicine (AIUM), the National Electrical Manufacturer's Association (NEMA), the guidelines of the United States Food and Drug Administration (FDA), and the guidelines of the International Electrotechnical Commission (IEC) in terms of safety and acoustic output levels. The ultrasound output levels are stated to permit the user to critically evaluate the system settings in the event of new research findings being announced.

#### **System Reference**

Acoustic Output Ch

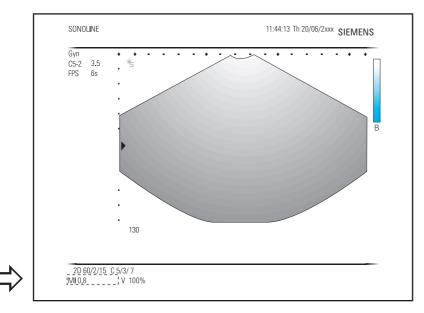
MARNING: Ultrasound procedures should be used for valid reasons, for the shortest period of time, and at the lowest mechanical/thermal index setting necessary to produce clinically acceptable images.

The ultrasound system incorporates an output display of *Mechanical and* **Thermal Indices** to allow you to monitor, and to limit, the amount of ultrasound energy that is transferred to the patient.

Note: For systems distributed in the United States of America, refer to the Medical Ultrasound Safety ultrasound education program brochure produced by the AIUM that is included in the System Reference.

# **Mechanical and Thermal Indices**

The system displays the Mechanical and Thermal Indices during real-time imaging, in all imaging modes, when the Mechanical Index or the Thermal Indices are equal to or exceed a value of 0.4.



Location of mechanical and thermal indices on the image screen.

#### Indices display in the abbreviated form shown below:

- MI: Mechanical Index
- TIB: Bone Thermal Index (fetal application)
- TIS: Soft Tissue Thermal Index
- Cranial Thermal Index TIC:

#### **System Reference**

Acoustic Output Ch 1

#### [1] Instructions for Use

Changing the Transmit Power 2-13 Transmit Power Display 2-14

#### **Transmit Power Control**

Adjust the transmit power and the corresponding acoustic pressure delivered through the transducer to the patient by using the designated control on the system. It is the main system function that determines the transmitted intensity of ultrasound for all transducers and imaging modes during real-time imaging, though it is not the only function that affects the mechanical and thermal indices. The range and especially the maximum level of the mechanical and thermal indices differ depending on the transducers. In addition, each diagnostic exam type has preset values for mechanical and thermal indices.

**Note:** Maximum transmit acoustic intensity and the mechanical index for each exam type are limited in accordance with the United States Food and Drug Administration's (FDA) recommendations and guidelines. System default transmit intensity and mechanical index values are always below the FDA recommendations for each exam type. Although some exam types may default to a condition of maximum allowable transmit power, there are other system controls or functions that could raise acoustic output levels.

#### To adjust the transmit power:

1. During real-time 2D-mode or M-mode imaging, press the **MENU** key on the control panel.

The system displays the default menu or the menu last viewed.

- 2. Roll the trackball to highlight the menu category (**2D** or **M**) at the top of the menu on the left of the screen and then press the **SET** key.
  - The system displays the list of available menu categories.
- 3. Roll the trackball to highlight **Tx** and then press the **SET** key.
- 4. To increase the transmit power, roll the trackball to highlight **Tx Power** and then press the **SET** key. You can alternately rotate the **SELECT** control when **Tx Power** is active.
- 5. To decrease the transmit power, roll the trackball to highlight **Tx Power** ♣ and then press the **SET** key. You can alternately rotate the **SELECT** control when **Tx Power** ♣ is active.
- 6. Press the **MENU** key to exit the menu.

#### [1] Instructions for Use

Functions Affecting Acoustic Output 2-15

# **Transmit Power Display**

The transmit power range is from –20 dB to 0 dB. Selecting 0 dB, or 100%, in combination with other system controls or functions generates the maximum acoustic intensity and mechanical index for each transducer, where:

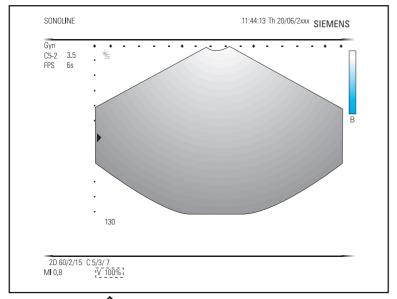
 $I_{SPTA,3}$ :  $\leq 720 \text{ mW/cm}^2 \text{ and MI} \leq 1.9$ 

Use the system presets to determine whether the power value displays on the image screen in decibels, **dB**, or as a **percentage** of the maximum allowable power.

0 dB	-3 dB	-6 dB	-9 dB	-12 dB	-15 dB	-18 dB	-21 dB	-24 dB
100%	71%	50%	35%	25%	18%	13%	9%	6%

Comparison of decibels to percentages.

When the power level is changed, the system briefly highlights the power value to indicate the change.



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Location of power display on the image screen.

#### **System Reference**

System Presets Ch 3



#### F6

General

► Beep Volume

►Tx Power Display Format

# **Imaging Functions that Change Acoustic Output**

△ **WARNING:** Observe the real-time display of mechanical and thermal indices (MI/TI) at all times.

In addition to the adjustment of the transmit power, adjustment of the following imaging functions and/or controls may affect the acoustic output:

- Automatic Time-out
- Exam Type
- Field of View (Scan Angle); 2D Steering Angle for linear array transducers
- Focus
- Frame Rate
- Resolution/Speed setting
- Density setting
- Freeze
- Image Depth
- Imaging Mode
- Multi-Frequency
- Power On/Off
- System Presets and QuickSets
- THI (using **MULTIHERTZ** control)
- Transducer
- Gel Pad Use

# **Transducer Surface Temperature Limits**

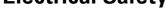
The following table provides the maximum surface temperature of the transducers compatible with the system.

Maximum surface temperatures are in accordance with IEC 60601-2-37.

	Maximum Temperature			
Transducer	TMM	Still Air		
C4-2	< 42.4° C	< 41.0° C		
C5-2	< 41.2° C	< 41.0° C		
C8-5	< 41.0° C	< 41.0° C		
7.5L75S	< 41.0° C	< 41.0° C		
L10-5	< 41.5° C	< 41.0° C		
EV9-4	< 41.6° C	< 41.0° C		
EC9-4	< 41.8° C	< 41.4° C		
Endo-V II	< 41.0° C	< 41.0° C		
Endo-P II	< 41.0° C	< 41.0° C		

TMM = Tissue Mimicking Material

# **Electrical Safety**



⚠ **WARNING:** For 115V systems: To ensure grounding reliability, only connect the system to a hospital-grade power outlet.

⚠ **WARNING:** The AC power connector plug for the ultrasound system is a three-prong grounded plug (in the U.S.A.) and should never be adapted to any two-prong (non-grounded) outlet, either by modifying the plug or by using an adapter. In the U.S.A., proper grounding requires the AC power connector plug to be plugged into a hospital-grade power outlet.

**WARNING:** To avoid electrical shock, never modify the ultrasound system's AC power connector plug, as doing so may overload your facility's power circuits. To ensure grounding reliability, connect the system only to an equivalent outlet.

**WARNING:** To avoid electrical shock, never use equipment that shows signs of wear or tampering, or whose ground plug has been bypassed using an adapter.

⚠ WARNING: Equipment connected to the ultrasound system and in the patient zone must be powered from a medically-isolated power source or must be a medically-isolated device. Equipment powered from a non-isolated source can result in chassis leakage currents exceeding safe levels. Chassis leakage current created by an accessory or device connected to a non-isolated outlet may add to the chassis leakage current of the ultrasound system.

▲ WARNING: Using an extension cord or multi-socket outlet setup to provide power to the imaging system, or to the system's peripheral devices may compromise the system grounding and cause your system to exceed leakage current limits.

⚠ **WARNING:** To avoid electrical shock and damage to the ultrasound system, power off and unplug the equipment from the AC power outlet before cleaning and disinfecting.

⚠ **WARNING:** Do not pour any fluid onto the ultrasound system surfaces, as fluid seepage into the electrical circuitry may cause excessive leakage current or system failure.

⚠ **WARNING:** To ensure proper grounding and leakage current levels, it is the policy of Siemens to have an authorized Siemens representative or Siemens-approved third party perform all on-board connections of documentation and storage devices to the ultrasound system.

⚠ **WARNING:** To maintain the safety and functionality of the ultrasound system, maintenance must be performed every 12 months. Electrical safety tests must also be performed at regular intervals as specified by local safety regulations, or as needed.

⚠ **Caution:** To avoid the possibility of static shock and damage to the system, avoid the use of aerosol spray cleaners on the monitor screens.

⚠ **Caution:** Do not use spray cleaners on the ultrasound system, as this may force cleaning fluid into the system and damage electronic components. It is also possible for the solvent fumes to build up and form flammable gases or damage internal components.

**EMC Note:** Operating the ultrasound system in close proximity to sources of strong electromagnetic fields, such as radio transmitter stations or similar installations may lead to interference visible on the monitor screen. However, the device has been designed and tested to withstand such interference and will not be permanently damaged.

# Level of Protection Against Electrical Shock • **Transducers**

⚠ **WARNING:** Only use Type BF transducers with the ultrasound system to maintain a level of protection against electrical shock.

According to EN 60601-1 and IEC 60601-1, the assemblies for the endocavity transducers, linear array transducers, and curved array transducers provide a "Level of Protection Against Electrical Shock" of "Type BF."



The Type BF icon is located on the transducer label.

# **Defibrillators**



⚠ WARNING: The ECG function is designed to withstand the effects of defibrillation. However, when possible, disconnect the ECG leads during defibrillation since a malfunction of the safety controls could otherwise result in electrical burns for the patient.

For patient safety, be sure to use defibrillators that do not have grounded patient circuits.

#### **Pacemakers**



A WARNING: Pacemakers may be susceptible to the high frequency electrical signal generated by ultrasound equipment. Use precautions when using ultrasound equipment on or near someone with a pacemaker. If there is interference, immediately discontinue the examination and power off the ultrasound system.

⚠ **WARNING:** Accessory equipment connected to the analog and digital interfaces must be certified according to the respective EN and IEC standards (for example, EN 60950 and IEC 60950 for data processing equipment and EN 60601-1 and IEC 60601-1 for medical equipment). Furthermore, all configurations shall comply with the system standards EN 60601-1-1 and IEC 60601-1-1. Anyone who connects additional equipment to any of the signal input or signal output ports configures a medical system and is therefore responsible that the system complies with the requirements of the system standards EN 60601-1-1 and IEC 60601-1-1. Siemens can only guarantee the performance and safety of the devices listed in the System Reference. If in doubt, consult Siemens service department or your local Siemens representative.

The ultrasound system is capable of supporting one on-board documentation device.

#### **System Reference**

Peripheral Equipment Ch 2, Ch 4

### **Ultrasound System • Care**

It is the responsibility of the user to verify that the ultrasound system is safe for diagnostic operation on a daily basis. Each day, prior to using the system, perform each of the steps in the Daily Checklist.

All exterior parts of the system, including the control panel, keyboard, transducers, and biopsy devices, should be cleaned and/or disinfected as necessary or between uses. Clean each component to remove any surface particles. Disinfect components to kill vegetative organisms and viruses.

The air filter on the ultrasound system must be cleaned regularly to maintain proper system cooling. Remove and check the air filter weekly, and clean as needed.

### **Daily Checklist**

#### Perform the following each day before using the ultrasound system:

☐ Visually inspect all transducers. Do not use a transducer which has a cracked, punctured, or discolored casing or a frayed cable.

**Discoloration Exception:** The use of Cidex OPA and Gigasept FF disinfectants may cause discoloration of transducer housings. You can continue to use a transducer if it is discolored due to the use of these specific disinfectants only.

☐ Visually inspect all power cords. Do not turn on the power if a cord is frayed or split, or shows signs of wear.

If your system's power cord is frayed or split, or shows signs of wear, contact your Siemens service representative for power cord replacement.

☐ Verify that the trackball, DGC slide controls, and other controls on the control panel are clean and free from gel or other contaminants.

#### Once the system is powered on:

- ☐ Visually check the on-screen displays and lighting.
- ☐ Verify that the monitor displays the current date and time.
- □ Verify that the transducer identification and indicated frequency are correct for the active transducer.

#### [1] Instructions for Use

Air Filters	2-27
Approved List	
of Disinfectants	2-35

#### Maintenance

MARNING: To maintain the safety and functionality of the ultrasound system, maintenance must be performed every 12 months. Electrical safety tests must also be performed at regular intervals as specified by local safety regulations, or as needed.

### Repair

For questions regarding repair or replacement of any equipment parts on your system, contact your Siemens service representative.

#### **Siemens Authorized Care**

Installers and operators must observe any statutory regulations that govern the installation, operation, inspection, and maintenance of this equipment.

To ensure the safety of patients, operators, and third parties, the equipment must be inspected every 12 months, and the replacement of parts is performed as necessary. This maintenance must be performed by a qualified Siemens authorized representative. It is important to inspect the equipment more frequently if it is operated under extraordinary conditions.

Perform inspections and maintenance at the prescribed intervals to avoid worn and hazardous parts due to wear. Contact the Siemens service department for information regarding the required maintenance. As manufacturers and installers of ultrasound equipment, Siemens cannot assume responsibility for the safety properties, reliability, and/or performance of the equipment, if:

- Installations, extensions, readjustments, modifications, additions, or repairs are carried out by persons not specifically authorized by Siemens.
- Components that affect the safe operation of the system are replaced by parts not authorized by Siemens.
- The electrical installation of the room where the equipment is located does not meet the power and environmental requirements stated in this manual.
- The equipment is not used in accordance with the operating instructions.
- The system is operated by personnel not adequately educated or trained.

Siemens suggests that you request any person who performs maintenance, or repairs, to provide you with a certificate showing:

- The nature and extent of the work performed
- Changes in rated performance
- Changes in working ranges
- Date of service
- Name of person or firm performing the service
- Signature of person performing the service

Technical documentation pertinent to the imaging system is available at an additional charge. However, this does not in any way constitute an authorization to conduct repairs or maintenance. Siemens refuses all responsibility whatsoever for repairs that are performed without the express written consent of the Siemens service department.

⚠ **WARNING:** Accessory equipment connected to the analog and digital interfaces must be certified according to the respective EN and IEC standards (for example, EN 60950 and IEC 60950 for data processing equipment and EN 60601-1 and IEC 60601-1 for medical equipment). Furthermore, all configurations shall comply with the system standards EN 60601-1-1 and IEC 60601-1-1. Anyone who connects additional equipment to any signal input or signal output ports configures a medical system and is therefore responsible that the system complies with the requirements of the system standards EN 60601-1-1 and IEC 60601-1-1. Siemens can only guarantee the performance and safety of the devices listed in the System Reference. If in doubt, consult Siemens service department or your local Siemens representative.

You must take all necessary precautions to eliminate the possibility of exposing patients, operators, or third parties to hazardous or infectious materials. Use universal precautions when cleaning and disinfecting. You should treat all portions of the imaging system that come in contact with human blood or other body fluids as if they were known to be infectious.

All exterior parts of the system, including the control panel, transducers, and biopsy devices, should be cleaned and/or disinfected as necessary or between uses. Clean each component to remove any surface particles. Disinfect the components to kill vegetative organisms and viruses.

### Cleaning and Disinfecting the System

⚠ WARNING: To avoid electric shock and damage to the system, always power
off and disconnect the equipment from the AC power source before cleaning
and disinfecting.

**WARNING:** Contents of some disinfecting agents are known to be health hazards. Their concentration in the air must not exceed an applicable specified limit. Comply with the manufacturer's instructions when using these agents.

**Caution:** To avoid the possibility of static shock and damage to the ultrasound system, avoid the use of aerosol spray cleaners on the monitor screens.

⚠ Caution: Do not use spray cleaners on the ultrasound system, or pour fluid onto the system surfaces, as fluid can seep into the system and damage electronic components. It is also possible for the solvent fumes to build up and form flammable gases or damage internal components.

Caution: Do not pour any fluid onto the ultrasound system surfaces, as fluid seepage into the electrical circuitry may cause excessive leakage current or system failure.

[1] Instructions for Use

Trackball Cleaning 2-26

#### **System Surfaces**

The following instructions describe cleaning the surface of the ultrasound system, including the trackball and transducer holder.

#### To clean the surface of the ultrasound system:

- 1. Power off (Ó) the ultrasound system and unplug the power cord from the power outlet.
- 2. Use a clean gauze pad or lint-free cloth, lightly moistened with a mild detergent, to wipe the surface of the ultrasound system.

Take particular care to clean the areas near the trackball and the slide controls. Ensure these areas are free of gel and any other visible residue.

Ensure that cleaning solution does not seep into the control panel, keyboard, or any other openings.

- 3. After cleaning, use a clean, lint-free cloth to dry the surface.
- 4. After cleaning, reconnect the ultrasound system power cord into the power outlet.

#### To clean the optional monitor filter:

- 1. Power off (O) the ultrasound system and unplug the power cord from the power outlet.
- 2. Use the cloth provided with the optional monitor filter to gently wipe the surface of the filter.

#### To clean the holders for transducers and coupling gel:

1. Remove the holder from the ultrasound system:

Reach under the holder to locate the tab on the holder. The tab extends below the point of attachment to the ultrasound system. Squeeze the tab towards the holder and pull the holder downward.

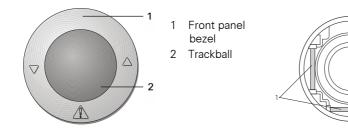
- 2. Clean the holder under running water, using a mild detergent and dry with a lint-free cloth.
- 3. Reattach the holder to the ultrasound system:

Align the support on the holder directly below the point of attachment on the ultrasound system and firmly push upwards until the holder snaps into place. [1] Instructions for Use

Holder attachment and detachment Ch 4

#### To clean the trackball:

- **Caution:** Do not drop or place foreign objects inside the trackball assembly. This may affect the trackball's operation and damage the system.
- 1. Remove the front panel bezel.
- 2. Remove the trackball.
- 3. Clean the trackball with tissue and isopropyl alcohol.
- 4. Clean the inside of the trackball assembly with a cotton swab and isopropyl alcohol, paying particular attention to the **X** and **Y** encoders and the idler wheel.
- 5. Allow the assembly parts to completely dry before reassembly.
- 6. Replace the trackball and front panel bezel.



Example of trackball assembly.

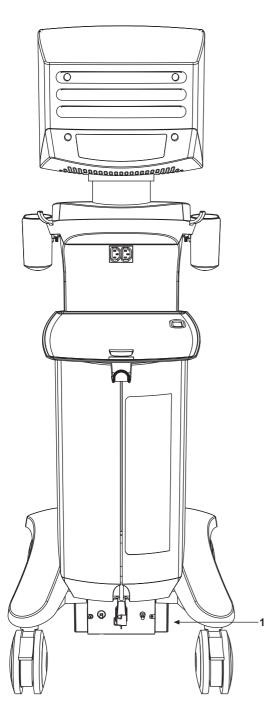
X and

Y encoders

Idler wheel

### **Cleaning an Air Filter**

The air filter on the ultrasound system must be cleaned regularly to maintain proper system cooling. Remove and check the air filter weekly, and clean as needed.



1 Location of Air Filter

Location of air filter.

#### To remove and clean the air filter:

- △ Caution: Do not scrub, stretch, or bend the filter, or apply heat to the filter, as doing so could damage the filter.
- 1. Power off and unplug the power cord from the power outlet.
- 2. Grasp the filter by its tab and pull it out of the slot.
- 3. Rinse the air filter with running water and allow the filter to completely dry.

To hasten drying, you may gently shake the filter, or blot the filter with a clean, lint-free cloth.

- $\triangle$  Caution: Do not insert a wet filter as this can damage the system.
- 4. Slide the air filter back into the ultrasound system.
- 5. Plug the power cord into the power outlet.

# **Documentation and Storage Devices** • Care

For information on the care of an optional documentation or storage device, please refer to the manufacturer's operating instructions that accompanied the device.

MARNING: Always place a sterile, non-pyrogenic transducer sheath on a transducer used in procedures requiring sterility.

MARNING: To minimize the risk of cross-contamination and infectious diseases, endocavity and intraoperative transducers must be cleaned and high-level disinfected after each use. A sterile, non-pyrogenic transducer sheath must be in place during procedures requiring sterility.

MARNING: There have been reports of severe allergic reactions to medical devices containing latex (natural rubber). Health care professionals are advised to identify latex-sensitive patients and to be prepared to treat allergic reactions promptly. For additional information in the U.S.A., refer to FDA Medical Alert MDA91-1.

⚠ WARNING: During neurosurgical procedures, if a transducer becomes. contaminated with tissue or fluids of a patient known to have Creutzfeld-Jacob disease, the transducer should be destroyed, as it cannot be sterilized.

MARNING: When using an endocavity or intraoperative transducer with a CF type applied part, the patient leakage currents may be additive.

⚠ WARNING: The outer surfaces of an endocavity or intraoperative transducer. should be checked to ensure there are no unintended rough surfaces, sharp edges, or protrusions that may cause a safety hazard.

△ Caution: Transducers are sensitive instruments – irreparable damage may occur if they are dropped, knocked against other objects, cut, or punctured. Do not attempt to repair or alter any part of a transducer.

△ Caution: To avoid cable damage, do not roll the system over transducer cables.

A Caution: To avoid damage to the transducer, do not use transducer sheaths containing an oil-based coating or petroleum- or mineral oil-based ultrasound coupling agents. Use only a water-based ultrasound coupling agent.

⚠ **Caution:** Follow all instructions provided by manufacturers of sterile goods (transducer sheaths) to ensure proper handling, storage, and cycling of all sterile goods.

Take extreme care when handling or storing transducers. They must not be dropped, jarred, or knocked against other objects. Do not allow transducers to come into contact with any sharp-edged or pointed object.

### **Cleaning and Disinfecting Transducers**

⚠ WARNING: To avoid electrical shock and damage to the system, disconnect the transducer prior to cleaning or disinfecting.

High-level disinfection 2-32 Immersion Levels 2-33

[1] Instructions for Use

⚠ **WARNING:** Disinfectants and cleaning methods listed are recommended by Siemens for compatibility with product materials, not for biological effectiveness. Refer to disinfectant label instructions for guidance on disinfection efficacy and appropriate clinical uses.

△ Caution: Do not sterilize transducers using hot steam, cold gas, or Ethylene Oxide (ETO) methods. Before applying any other methods which might be recommended by manufacturers of sterilization equipment, please contact your Siemens representative.



△ Caution: To avoid damage to the transducer, observe the immersion levels indicated for each transducer type. Do not immerse or allow the cable or connector of a transducer to become wet.



△ Caution: The transducers have been designed and tested to be able to withstand high-level disinfection as recommended by the manufacturer of the disinfectant product. Carefully follow the disinfectant manufacturer's instructions. Do not immerse for more than one hour.



△ Caution: Do not use abrasive cleaning agents, organic solvents such as benzene, isopropyl alcohol, or phenol-based substances, or cleaning agents containing organic solvents to clean or disinfect transducers. These substances can damage the transducers.



**Caution:** Do not use a spray cleaner on a transducer, as this may force cleaning fluid inside the housing and damage the transducer.

All transducers should be cleaned and disinfected prior to their use on each patient. Endocavity and intraoperative transducers require high-level disinfection prior to use.

#### To clean and disinfect a transducer:

- 1. Disconnect the transducer from the system.
- 2. Moisten a clean gauze pad with water and wipe the transducer to remove any gel or particles remaining on the transducer.
- 3. Carefully wipe the entire transducer, including the cable and connector.
- 4. To disinfect the transducer, take care to keep the cable strain relief and connector of the transducer dry while immersing the transducer in an approved disinfectant to the level indicated in the following illustration.
- 5. Carefully follow the disinfectant manufacturer's instructions.
- 6. After cleaning or disinfecting, use a clean cloth to dry the transducer.

#### To high-level disinfect a transducer:

- 1. Disconnect the transducer from the system.
- 2. Thoroughly clean, rinse, and dry the transducer.
- 3. Take care to keep the cable strain relief and connector of the transducer dry while immersing the transducer in an approved disinfectant to the level indicated in the following illustration.
- 4. Carefully follow the manufacturer's instructions for high-level disinfection.
- 5. After high-level disinfecting, use a clean cloth to dry the transducer.

### **IPX8 Immersion Levels**

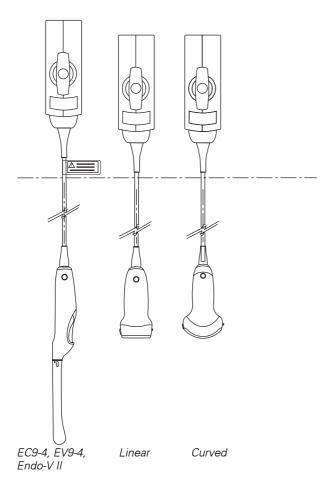
△ Caution: To avoid damage to the transducer, observe the immersion levels indicated for each transducer type. Transducers with the protection level IPX8 are indicated by the presence of the "IPX8" symbol on the connector of the transducer. If a transducer does not have the "IPX8" symbol on the connector of the transducer, then observe the immersion levels provided in the illustration for Non-IPX8 transducers.

Transducers meet Ingress Protection level IPX8 of EN 60539 and IEC 60539 to the depth of the immersion line shown in the illustration only for transducers with the "IPX8" symbol on the connector of the transducer.



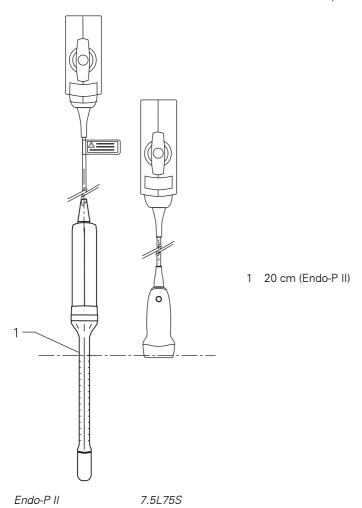


Example of transducer labels with IPX8 symbol.



IPX8 Immersion Levels.

△ Caution: To avoid damage to the transducer, observe the immersion levels indicated for each transducer type. Transducers without the protection level IPX8 do not have the "IPX8" symbol on the connector of the transducer. If a transducer does not have the "IPX8" symbol on the connector of the transducer, then observe the Non-IPX8 Immersion Level illustration,



Non-IPX8 Immersion Levels.

Note: Non-IPX8 transducers meet Ingress Protection level IPX7 to the depth of the immersion line shown in the above illustration.

### **Approved List of Disinfectants**

The following matrix provides a list of approved disinfectants for all transducers.

**Note:** Cidex OPA and Gigasept FF may discolor transducer housings. There is no associated degradation of imaging performance or transducer reliability.

	Cidex	Cidex Plus	Cidex OPA	Milton	Virkon	Gigasept FF
C4-2	✓	✓	✓	✓	✓	✓
C5-2	✓	✓	✓	✓	✓	✓
C8-5	✓	✓	✓	✓	✓	✓
7.5L75S	✓	✓	✓	✓	✓	✓
L10-5	✓	✓	✓	✓	✓	✓
EC9-4	✓	✓	✓	✓	✓	✓
EV9-4	✓	✓	✓	✓	✓	✓
Endo-V II	✓	✓	✓	NC	✓	✓
Endo-P II	✓	✓	NA	NA	NA	✓

<sup>√ =</sup> compatible

NC = not compatible

NA = not applicable (not tested)

### **Storage**

Store transducers in a clean and dry environment. Extreme temperatures or humidity may damage a transducer.

### Repair

Do not attempt to repair or alter any part of the transducer. Contact your service representative at Siemens immediately if a transducer appears to be damaged or malfunctions in any way.

#### **Protective case**

Due to the mechanical sensitivity of transducers, Siemens recommends that you always use the transducer case when you ship a transducer or transport it from one place of examination to another. The case is specially designed to protect the sensitive parts of the transducer. Be sure that all parts of the transducer are properly placed inside the case before you close the lid.

# [1] Instructions for Use System Care 2-21

Ch 6

Temperatures

### Transducer Accessories • Care

MARNING: Ensure the accessories for a transducer are properly cleaned, sterilized or disinfected as appropriate before each use to avoid possible patient contamination.

[2] Instructions for Use

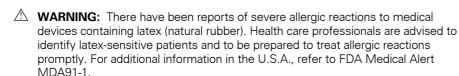
Attachment Procedures

Ch C1

Instructions for care are provided for the following accessories for transducers:

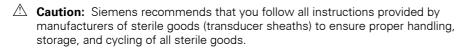
- Transducer Sheaths
- Gel pads
- Needle Guide Bracket Kits

### **Transducer Sheaths**



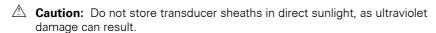


⚠ WARNING: To minimize the risk of cross-contamination and infectious diseases, endocavity transducers must be cleaned and high-level disinfected after each use. A sterile, non-pyrogenic transducer sheath must be in place during procedures requiring sterility.



Using a disposable latex transducer sheath on a transducer reduces the possibility of cross-contamination. Always use a protective transducer sheath for endocavity exams, and when scanning an open wound or an area where the skin is not intact.

### **Storage**



Latex products have a limited shelf life, and should be stored in a cool, dry, dark place with an ambient temperature between -5°C and +40°C and up to 80% relative humidity at +40°C. Before use, examine these products for any material flaws. Some packaging may list an expiration date. Any product showing flaws, or whose expiration date has passed, should not be used.

Before use, examine the gel pad for any material flaws. Thinning, bulging, or brittleness of the material indicates damage. Any product showing flaws should not be used.

### **Storage**

Do not store gel pads below 5°C nor above 57°C. Gel pads have a limited shelf life. Before use, examine these products for any material flaws. Some packaging may list an expiration date. Any product showing flaws, or whose expiration date has passed, should not be used.

### **Needle Guide Bracket Kits**

⚠ WARNING: If a needle guide becomes contaminated with tissue or fluids of a patient known to have Creutzfeld-Jacob disease, then the needle guide should be destroyed. Sterilization is not effective against Creutzfeld-Jacob contamination.

Needle guide bracket kits are available for biopsy and puncture procedures for specific transducers.

#### [2] Instructions for Use

Compatible

Ch C1 Transducers

### Storage and Transportation

Always clean and sterilize or high-level disinfect components used in a needle puncture or biopsy procedure after each use.

### Cleaning, Disinfecting, and Sterilizing • Needle **Guide Bracket Kits**

#### **EC9-4 Disposable Endocavity Needle Guide**



⚠ WARNING: The needle guide is packaged sterile and is a single-use item. Do not use if the packaging indicates signs of tampering or if the expiration date has passed.

The disposable endocavity needle guide is a single-use item. Refer to the in-box instructions for disposal instructions.

#### EC9-4 Stainless Steel Endocavity Needle Guide



⚠ WARNING: Needle Guide Bracket kits are packaged non-sterile. Sterilize these products prior to their first use.

The stainless steel endocavity needle guide is a reusable item. Refer to the in-box instructions for attachment and care procedures, including cleaning and sterilization.

#### 6.5EV13 Needle Guide Bracket Kit (EV9-4)

⚠ WARNING: Needle Guide Bracket kits are packaged non-sterile. Sterilize these products prior to their first use.

#### To clean:

- 1. Rinse the guide under water, and then scrub the inside of the guide with a brush.
- 2. Visually inspect the guide to make sure all debris is removed.

#### To sterilize:

- 1. Prior to sterilization, clean the needle guide.
- 2. Sterilize holders and needle guides using steam at a temperature of 121°C to 123°C for an exposure time of 15 to 30 minutes. This is a gravity-displacement steam sterilization method.

#### **Endo-V II Needle Guide Bracket Kit**

⚠ WARNING: Needle Guide Bracket kits are packaged non-sterile. Sterilize these products prior to their first use.

#### To clean:

- 1. Rinse the guide under water, and then scrub the inside of the guide with a brush
- 2. Visually inspect the guide to make sure all debris is removed.

#### To sterilize:

- 1. Prior to sterilization, clean the needle guide.
- 2. Sterilize holders and needle guides using steam at a temperature of 121°C to 134°C for an exposure time of 15 to 30 minutes. This is a gravity-displacement steam sterilization method.

#### **Endo-P II Needle Guide Bracket Kit**

#### To clean:

- 1. Rinse the guide under water, and then scrub the inside of the guide with a brush.
- 2. Visually inspect the guide to make sure all debris is removed.

#### To sterilize:

- 1. Prior to sterilization, clean the needle guide.
- 2. Sterilize holders and needle guides using steam at a temperature of 121°C to 123°C for an exposure time of 15 to 30 minutes. This is a gravity-displacement steam sterilization method.

### S-Array Needle Guide Bracket Kit (7.5L75S)

⚠ WARNING: Needle Guide Bracket kits are packaged non-sterile. Sterilize these products prior to their first use.

#### To clean:

- 1. Rinse the guide under water, and then scrub the inside of the guide with a brush.
- 2. Visually inspect the guide to make sure all debris is removed.

#### To sterilize:

- 1. Prior to sterilization, clean the needle guide.
- 2. Sterilize holders and needle guides using steam at a temperature of 121°C to 123°C for an exposure time of 15 to 30 minutes. This is a gravity-displacement steam sterilization method.

#### **Universal Needle Guide, Stainless**

▲ WARNING: Needle Guide Bracket kits are packaged non-sterile. Sterilize these products prior to their first use. Refer to the sterilization procedures for the Universal Needle Guide in the following pages.

Prior to sterilization, clean the universal needle guide bracket and insert(s) using an enzymatic cleaner.

#### To clean:

- 1. Rinse the bracket and insert(s) with water.
- 2. Soak the bracket and insert(s) in an enzymatic cleaner.
  - Carefully follow the manufacturer's instructions.
- 3. Rinse the bracket and insert(s) with water to remove any debris and remaining cleaner.

#### To sterilize:

 Sterilize the bracket and needle guide insert(s) using a wrapped, gravity-displacement steam sterilization at a temperature of 121°C to 123°C for an exposure time of 15 to 30 minutes.

### **Storage**

Always clean and sterilize components used in a needle puncture or biopsy procedure after each use.

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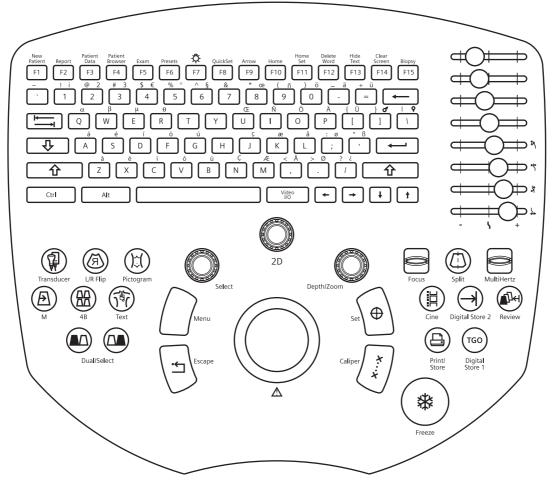
### **Control Panel**

The controls for all imaging modes, parameters, documentation, and system selections are designed to promote quick learning and recognition of the controls and functions. The ultrasound imaging system has a combination of keys, rotary knobs, push and rotate controls, push controls, and function keys. A trackball provides direct access to calipers, menu items, and other imaging functions. These keys and controls are logically arranged to require a minimum number of hand and eye movements.

[1] Instructions for Use

Keyboard 3-20

Language overlays for the control panel are available. The locations and functions of the keys and controls are not impacted by the overlay.



Example of the control panel on the ultrasound imaging system.

### **Control Panel Lighting**

When the imaging system is in use, all controls on the main control panel are back-lit. The system increases the lighting intensity of most active controls to show you, at a glance, which functions are active.

The LED lamps located under the front of the monitor provide additional task lighting. Use the **F7** key on the keyboard to turn the task lighting on and off.

### **Control Panel Audio Signal**

Use the system presets to deactivate or adjust the volume of the beep.

### **Trackball**

The trackball is the main interactive tool used to position image graphics and text, and make selections from onscreen menus. You can use the trackball in conjunction with the keys and controls located on the control panel, including menu selections.

#### **System Reference**

System Presets

Ch 3



F6

General

▶ Beep

► Beep Volume



Trackball.

### **Trackball Assignment**

When a particular function is active, the system assigns the trackball to a specific task. The active tool or function currently under trackball control is represented by a highlighted icon on the lower right of the screen. The system may display additional icons for previously activated tools or functions. You can reassign the trackball to another tool or function by selecting the related trackball icon on the image screen or by pressing the **SELECT** key on the control panel (when multiple icons are displayed on the image screen).

**Note:** The system cannot assign the trackball to more than one tool or function.

Trackball Icon	Trackball Assignment (when highlighted)
=	Positioning the A-mode cursor or M-mode cursor
+ -k´,	Positioning of measurement markers
H	Selecting the frame in CINE for review
	Positioning inflection points on a map
	Selecting menu items (trackball pointer)
	Adjusting the width of the image
	Adjusting the position of the image
	Positioning the image with the Offset function
A <sub>C</sub>	Positioning a cursor for text annotation, including arrow placement
=== 7	Selecting pictograms
R	Positioning the Region of Interest (ROI) for image magnification (zoom)

A dual-function control that activates one function when the control is pressed and another function when the control is rotated. When several functions are active, you can assign control of the trackball to any of the active functions by pressing the **SELECT** control.



During mixed-mode imaging, you can press the **SELECT** control to reassign the trackball from controlling a function for one mode (for example, 2D FOV) to controlling a function for another mode (for example, the M-mode cursor).

During the measurement function, you can use the **SELECT** control to delete portions of a measurement. Rotating the control when a trace measurement or drawing in a patient report is active causes the system to delete the line, one dot at a time.

#### To assign the trackball:

- 1. Press the **SELECT** control.
  - The active function currently under trackball control is represented by a highlighted icon on the lower right of the screen.
- 2. To cycle through the available functions, continue to press the **SELECT** control.
- 3. Rotate the **SELECT** control within a function to access its corresponding settings, pages, or values.

### **Caliper**

Activates the Measurement function.

When you press the **CALIPER** key, the menu displays measurement selections appropriate for the imaging mode and exam type. The system also places the first marker in a *caliper* set (set of measurement markers) in the image area.

The Measurement function can generate a patient report for exam types with a report.

Use the system presets to automatically activate the Measurement function each time you press the **FREEZE** key.

### **Freeze**

Freezes the image or sweep on the screen. If an image or sweep is already frozen, pressing the **FREEZE** key restores real-time imaging.

Use the system presets to change the response of the **FREEZE** key to activate the CINE function or the Measurement function. Other assignments for this key include text annotation or pictograms.

Pedal 1 on the footswitch is programmed with the same functionality as the **FREEZE** key.



Caliper.

#### **System Reference**

System Presets Ch 3



#### F6

Default Settings
► Automatic Freeze
Response



Freeze.

### **Selection and Entry Keys**

The **ESCAPE** and **SET** keys are located in close proximity to the trackball and provide additional functionality to the trackball and SELECT control for interacting with onscreen information and objects.

### **Escape**

Exits the currently displayed mode, function, or page and reactivates the previous mode, function, or page.

Pressing the ESCAPE key, while in the Measurement function, exits the function and erases all measurements.



#### Set

The **SET** key confirms the selection of a specific function or command. For example, you can use it to anchor calipers, select a menu item or image graphic, cycle through certain menu settings, include a measurement value in a patient report, or delete a measurement from the worksheet.



When used with the trackball, the function of the SET key is similar to a mouse-modeclick in the system's Windows <sup>®</sup> -based technology.

#### Menu

Displays menu selections on the left of the screen for the active mode or function.



Menu.

### 2D-Mode and M-Mode Imaging Controls

Use the imaging controls to activate an operating mode, change the image orientation, or modify the sweep display.

#### **2D**

A dual-function control that activates one function when the control is pressed and another function when the control is rotated.

Pressing the **2D** control activates 2D-mode for grayscale imaging. If a mixed mode or imaging function is active, pressing **2D** causes the system to exit the mode or function and return to 2D-mode.

Rotating the **2D** control changes the overall gain for the active mode. Rotating the **2D** control clockwise increases the gain; a counterclockwise rotation decreases the gain.

The range for gain settings is from 0 dB to 40 dB. When combined with the DGC controls, a gain range of –15 dB to 55 dB is possible.

### **Split**

Creates side-by-side images from one 2D-mode image. The two images are simultaneously frozen or real-time.

Certain post-processing imaging parameters can be changed in the right image, allowing you to compare the effects of different image settings on an anatomical structure.





#### **Dual/Select**

Activates Dual-mode, which displays two separately acquired images, side-by-side.

The **DUAL/SELECT** control consists of a set of two keys. The left key displays an image on the left side of the screen. The right key displays an image on the right side of the screen. Use either key to initiate Dual-mode.



Only one image can be active at any one time. The active image is indicated by the lighting intensity of the selected key and by the brightened active image indicator that displays on the image screen.



The **DUAL/SELECT** control can be used to toggle the active image. Pressing the left key activates the left image and freezes the right image. Pressing the right key activates the right image and freezes the left image.

**Note:** The system displays a full screen image when the key for the active image is pressed. The system restores the side-by-side display when this key is pressed again.

Most imaging parameters can be changed independently.

#### **4B**

Activates 4B-mode which displays four separately acquired 2D-mode images.

Only one image is active at a time. The active image is indicated by the brightened active image indicator.

Pressing the **4B** key displays the first image on the upper left side of the screen. Pressing the **FREEZE** key freezes the active image and displays the next image. A total of four images can be displayed. Press the **4B** key repeatedly to cycle through and activate images.



Most imaging parameters can be changed independently.

For software versions 2.0 and higher: Pressing the **4B** key when the (DIMAQ) Image screen is displayed activates simultaneous display of marked images.

#### M

Activates M-mode.

Pressing the **M** control displays an M-mode cursor in a 2D image. You can then roll the trackball to place the cursor in the area of interest. Pressing **M** a second time displays 2D/M-mode.



### L/R Flip

Changes the scan direction of the active transducer. The image can be acquired from right-to-left or left-to-right.



Pressing **L/R FLIP** while pressing and holding the **Shift** key on the keyboard rotates the image 90 degrees in the clockwise direction.

L/R Flip

The location of the active image indicator defines the direction of scanning.

For software versions 2.0 and higher: Pressing the **L/R FLIP** key when the (DIMAQ) Image screen is displayed marks the selected image for simultaneous display.

## **Image Parameter Controls**

#### **Transducer**

Activates a transducer.

Press **TRANSDUCER** repeatedly to cycle through the transducers connected to the system. The name of the active transducer displays on the screen.



#### MultiHertz

Changes the transmit frequency of an active multi-frequency transducer in all modes.

Push the **MULTIHERTZ** control to cycle through the available frequencies. Pushing the control up increases the frequency, and pushing the control down decreases the frequency.



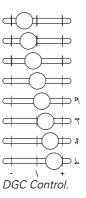
#### MultiHertz.

#### **DGC**

Increases or decreases the received gain for the depth of view. The receiver gain range is depth-dependent for the active transducer frequency.

The system can display a graphic representing the DGC curve on the image screen.

Use the system presets to select the length of time that the DGC graphic displays on the image screen. The **2D** control also affects system gain.





#### F6

Display

▶ DGC Curve

Display

General

▶ DGC Invert with

Image Invert

#### Depth/Zoom

A dual-function control that activates one function when the control is rotated and another function when the control is pressed and then rotated.

Rotating the **DEPTH/ZOOM** control changes the imaging depth.

Use the system presets to assign the direction of rotation (clockwise or counterclockwise) for increasing a value when using the **DEPTH/ZOOM** control. This assignment affects both the depth and zoom parameters.

The depth scale displays in millimeters (mm), and the current depth setting displays on the lower left of the image screen.

Pressing **DEPTH/ZOOM** activates a zoom window in the image, initiating the magnification process. Zoom is available in real-time or when the image is frozen.

Rolling the trackball positions the zoom window over the region of interest (ROI). Rotating **DEPTH/ZOOM** adjusts the size of the window. Pressing **DEPTH/ZOOM** again magnifies the selection. To exit zoom, press the **2D** control.

When Zoom is activated, the ROI of a real-time or frozen image can be moved by rolling the trackball.



#### **System Reference**

System Presets

Ch 3



F6

Customize Keys
►Zoom/Depth
Direction

The **FOCUS** control positions the transmit focal zones in the image. One, two, or four focal zone markers can be positioned at the same time.

**Note:** When two or four focal zones are used, a reduction in frame rate occurs. The amount of reduction depends on the depth of view and the transducer in use.

Push the **FOCUS** control up or down to position the focal zone markers that represent the focal zone locations.

#### One (1)

You can position the marker throughout the field of view.

#### Two (2)

The spacing between the two focal zones adjusts automatically.

#### Four (4)

The **FOCUS** control adjusts the relative position of the focal zone markers within the field of view. The spacing between the focal zones adjusts automatically.

#### **Pictograms and Annotation**

Use the pictogram and annotation controls to display text and graphics depicting anatomical structures onscreen.

#### **Text**

Allows access to tools for positioning, entering, and editing text on the image screen. You can enter text from the keyboard or select from a set of descriptive anatomical terms on the onscreen menu.

Press the **TEXT** key to display a cursor on the screen for direct text entry using the keyboard. To reposition the text cursor, roll the trackball. To display the terms assigned to the current exam type, press the **MENU** key. Roll the trackball to the required term and then press the **SET** key. Press the **ESCAPE** key to remove text displayed on the screen.

Use the system presets to customize the text assigned to an exam type.

#### **Pictogram**

**Pictograms** are onscreen anatomical graphics that indicate the anatomy under evaluation and the orientation of the transducer. Pictograms can also be included in patient reports for some exam types.

Pressing the **PICTOGRAM** key displays the pictograms assigned to a specific exam type on the screen.

Use the system presets to customize the pictograms assigned to an exam type.

To select a pictogram, roll the trackball to position the pointer on the required pictogram and then press the **SET** key. Press the **ESCAPE** key to remove the pictogram displayed on the screen.

Some pictograms contain a transducer marker. Use the **SELECT** control to rotate the transducer marker. To reposition the marker, roll the trackball. To anchor the marker, press the **PICTOGRAM** key again.

#### [2] Instructions for Use

Annotations Pictograms Ch A1 Ch A1



#### System Reference

System Presets

Ch 3



#### F6

Default Settings
► Pictogram List
► Text Annotation



Pictogram.

#### **Documentation Controls**

Use the documentation controls to access recording devices for printing, storing, or retrieving images and imaging parameters.

#### F6

Customize Keys

#### **Print Store**

Stores or prints the displayed image or report to the destination configured in system presets.

Use the system presets to assign functionality to this control. For example, you can configure the control to:

Send onscreen information to an installed documentation device, such

## Print Store.

## as the black and white printer.

#### **Digital Store 1**

Stores or prints the displayed image or report to the destination configured in system presets.



Use the system presets to assign functionality to this control. For example, you can configure the control to:

Digital Store 1.

- Send onscreen information to an installed documentation device, such as the black and white printer.
- Activate the TGO (Tissue Grayscale Optimization) optional feature.
- Store clips. (Requires the Clip Store optional feature.)

#### **Digital Store 2**

Stores or prints the displayed image or report to the destination configured in system presets.



Use the system presets to assign functionality to this control. For example, you can configure the control to:

- Send onscreen information to an installed documentation device, such
- Activate the TGO (Tissue Grayscale Optimization) optional feature.
- Store clips. (Requires the Clip Store optional feature.)

as the black and white printer.

#### **Review**

Accesses the DIMAQ-IP feature to view images and reports, either during a patient examination or from saved studies.

## **Special Function Controls**

#### **CINE**

Activates the CINE function and displays CINE menu selections.

Use the system presets to automatically activate the CINE function each time you press the  ${\bf FREEZE}$  key.







#### **System Reference**

System Presets

Ch 3



#### F6

Default Settings
► Automatic Freeze
Response

Use the alphanumeric keyboard for entering patient data, selecting an exam type, annotating clinical images, and configuring the system presets.

The keyboard is arranged like a standard computer keyboard. A description of the function keys and other special keys follows.

## **Shortcut Keys**

The system supports "shortcuts" through combining keys on the keyboard.

To use a shortcut, press and hold the first key and then press the second key. For example, to use the shortcut Ctrl+U, press and hold the Ctrl key and then press the **U** key.

Use the system presets to activate functions without using shortcuts (not available for all functions).

Shortcut (Key Combination)	Function
Ctrl+D <sup>1</sup>	During the measurement function, activates the Delete feature for removing measurements from the screen.
Ctrl+M <sup>1</sup>	During the measurement function, activates the Modify feature for editing measurements.
Ctrl+P	Hides or displays patient information on the screen.
Ctrl+U <sup>1</sup>	<ul> <li>Enables or disables automatic printing of the displayed image to the selected USB printer when you store the image to the ultrasound system's hard disk using a documentation control.</li> </ul>
	<b>Note:</b> Use the system presets to install printers, select printers, and enable or disable automatic printing.
	<ul> <li>During the measurement function, removes the label assignment from the last measured value (activates the Undo feature).</li> </ul>

#### [2] Instructions for Use

Measurements and Ch B1 Calculations

#### System Reference

System Presets Ch 3



#### F6

Patient ID ► Hide Patient Demographic DIMAQ Utility ► Autoprint Images

<sup>&</sup>lt;sup>1</sup> Requires software version 2.0 or higher

## **Special Characters**

The system supports some language's special characters through the use of a combination of keys on the keyboard.



The **ALT** key located on the left side of the keyboard accesses the special characters located on the upper right of a key.



The **SHIFT** key located on the left or right side of the keyboard accesses the special characters located on the upper left of a key.

German		French	
Character	<b>Key Combination</b>	Character	Key Combination
Ä	ALT p	Ç	ALT n
ä	ALT -	ç	ALT j
ö	ALT 0 (zero)	à	ALT z
Ü	ALT [	è	ALT x
ü	ALT =	é	ALT s
ß	ALT '	ù	ALT b
Spanish		Italian	
Character	Key Combination	Character	Key Combination
i	ALT 1	à	ALT z
خ	ALT /	è	ALT x
Ñ	ALT I	é	ALT s
ñ	ALT 9	ì	ALT c
á	ALT a	ò	ALT v
é	ALT s	ù	ALT b
ĺ	ALT d		
ó	ALT f		
ú	ALT g		
Scandinavia	n	Other	
Character	Key Combination	Character	Key Combination
Æ	ALT m	Œ	ALT u
æ	ALT k	œ	ALT 8
Ø	ALT . (period)	α	ALT q
Ø	ALT ;	β	ALT w
Å	ALT ,	μ	ALT e
å	ALT I	θ	ALT r

The  ${\bf F}$  keys located in a row across the top of the alphanumeric keyboard are called *function keys*.

#### F1 - New Patient

Displays the first page of a new Patient Data entry form.

F1

### F2 - Report

Displays the patient report if one is available for the current exam type. You can view, edit, or print the report.



#### F3 - Patient Data

Displays the Patient Data form currently in use. You can view or edit the page.



#### F4 - Patient Browser

Accesses the DIMAQ-IP feature to view images and reports, either during a patient examination or from saved studies.



#### F5 - Exam

Displays a list of available system-defined exam types and user-defined QuickSets.



#### F6 - Preset Menu

Displays the first page of the **Preset Main Menu**. Use the system presets to modify and customize the system, including general settings, QuickSets, image annotation, and calculation settings.

F6

You can use the **F6** key to exit the system presets.

## F7 – ☼ (Task Light)

Illuminates the keyboard using lights on the underside of the monitor.

F7

#### F8 - QuickSet

Accesses the screen for saving, deleting, and overwriting QuickSets (a configuration of imaging settings for a specific transducer and exam type).

F8

#### F9 - Arrow

Places an arrow on the screen. Roll the trackball to reposition the arrow. Press the **SET** key to anchor the arrow's position.

F9

#### F10 - Home

Places the text cursor in the Home position (as defined with the **F9** key) when the Annotation function is active.

F10

Sets the default location of the text cursor. After pressing the **TEXT** key on the control panel, roll the trackball to place the text cursor on the image screen in the desired location and then press the **F11** key. When the **HOME** key on the keyboard is pressed, the system places the text cursor in the position defined with the **F11** key.

F11

#### F12 - Delete Word

Removes the most recently added term from the screen.

F12

#### F13 - Hide Text

Hides annotations. Press **F13** again to display the annotations.

F13

#### F14 - Clear Screen

Deletes all text annotation displayed in the image area. Pressing the **F14** key does not delete pictograms.

F14

#### F15 - Biopsy

Displays biopsy/puncture guidelines on the image screen for specific transducers and provides system selections for selecting and modifying the guidelines.

F15

Use the system presets to enable the Biopsy function to automatically activate when an exam type is selected.

F6

You can use the **F15** key to exit the Biopsy function.

Default Settings ► Biopsy

## **Other Alphanumeric Keys**

#### **Arrows**

Repositions the text cursor in the direction shown on the arrow key.



#### **Alt**

Accesses special characters on the upper right of the keys located on the keyboard.



#### **Backspace**

Deletes one character at a time from right to left during text entry.



Deletes lines of completed text, one at a time. (You must press and hold the **BACKSPACE** key.)

#### **Caps Lock**

Locks all keyboard letter keys in upper case.



#### Ctrl

For software versions 2.0 and higher: When used in a shortcut (key combination), activates the related function.



For example, when used in the shortcut **Ctrl+U**, enables or disables automatic printing of the displayed image to the selected USB printer (when you store the image to the ultrasound system's hard disk using a documentation control).



#### **Enter**

Accepts entered data.



Accesses the upper-case letters and the character on the upper left of a key located on the keyboard.



#### **Space Bar**

Inserts a blank space.

#### Tab

Moves the cursor to the beginning of the next available entry field in the *Patient Data* form or a patient report.



#### Video I/O

Displays a video signal that originates from an outside source, such as a VCR, on the system monitor.



Use the system presets to select the video input source.



System Presets Ch 3



#### F6

Peripheral

#### **Footswitch**

Use the optional footswitch as an alternative to operating keys on the control panel. Pedal 1 is assigned to the Freeze/Unfreeze function; pressing this pedal is equivalent to using the **FREEZE** key on the control panel. Use the system presets to assign Pedal 2 to one of the following functions:

- Print to a black and white printer.
- Store to the system's hard disk.
- Store clips to the system's hard disk.<sup>1</sup>

### **Menu Selections**

The system displays onscreen menu selections for the active mode or function on the left of the screen when you press the **MENU** key.

#### **Transmit Power Selections**

You can access the transmit power selections from the 2D-mode Imaging menu or the M-mode Imaging menu.

Selection	Description	Settings
Tx Powerû	Increases the transmit power level and the corresponding acoustic pressure delivered through the transducer to the patient.	0 dB to -20 dB or 100% to 10%
Tx Power <b></b>	Decreases the transmit power level and the corresponding acoustic pressure delivered through the transducer to the patient.	0 dB to –24 dB or 100% to 6%

#### **System Reference**

System Presets Ch 3



Customize Keys ▶ Pedal 2 function

3 - 27

<sup>&</sup>lt;sup>1</sup> Requires software version 2.0 or higher

## **2D-Mode Selections**

Selection	Description	Settings
TGO	Automatically optimizes the overall field of view (FOV) image brightness uniformity by changing the DGC, overall gain, and lateral gain.	On, Off
TGO Refresh	Re-activates TGO (Tissue Grayscale Optimization).	
TGO Gain <sup>1</sup>	Specifies an offset value for preferred image brightness with TGO during an examination (for the current exam type and transducer). The selected value represents the increments of gain adjustment to be added to or subtracted from the default setting for the optimized gain.	-40 to 40 in increments of 1
<b>DR</b> (Dynamic Range)	Controls the overall contrast resolution of 2D-mode images.	35 dB to 70 dB in 1 dB increments
Persistence	Creates a visible smoothing effect by maintaining more lines of image data for each frame of imaging when the setting is increased.	0, 1, 2, 3, 4, 5, 6, 7
Edge	Distinguishes the edges of a structure.	0, 1, 2, 3, 4, 5
Gray Map	Selects a gray (processing) map.	L, B, E, S, D, A, C
Focus	For all curved or linear transducers, selects the number of focal zones.	1, 2, or 4
	Use the <b>FOCUS</b> control on the control panel to position the markers.	
FOV/POS	Resizes and repositions the field of view using the trackball.	On, Off
A-mode	Activates or deactivates A-mode.	On, Off
Reset Map	Resets the current Gray Map curve back to the original factory position.	_
Modify Map (Processing)	Allows changes to the shape of the current Gray Map with the exception of Map L.	
Reject	Increases or decreases the level of gray shades eliminated from the image.	0 to 64 in increments of 2
Offset	Enables horizontal and vertical scrolling of the image using the trackball.	On, Off
Steer	For linear array transducers only, steers the 2D image to the left, center, or right.	L, C, R
SynAps	Extends the focal zone.	On, Off
	This selection is available for curved and linear array transducers.	
Density	Increases or decreases the acoustic scan line density of a 2D image.	Std (Standard) or Hi (High)
Res/Speed	Increases image resolution by decreasing frame rate.	Std/Dtl/Far

<sup>&</sup>lt;sup>1</sup> Requires software version 2.0 or higher

## **M-Mode Selections**

Selection	Description	Settings
<b>DR</b> (Dynamic Range)	Controls the overall contrast resolution of M-mode sweep.	35 dB to 70 dB in 5 dB increments
Edge	Edge Enhancement. Distinguishes the edges of a structure.	0, 1, 2, or 3
Reject	Increases or decreases the level of gray shades eliminated from a sweep.	0 to 64 in increments of 1
Gray Map	Selects an M-mode gray map.	L, B, E, S, D, A, C
Full M	Displays a full-screen M sweep.	On, Off
<b>Sweep Sp</b> (Sweep Speed)	Adjusts the scrolling speed of the M-mode sweep. The unit is seconds.	2, 4, 8, 16

## **CINE Selections**

Selection	Description
Frame Review	Displays individual frames in a forward or reverse direction, in response to the trackball. Frame numbers are displayed.
	For M-mode, one frame of time motion data is displayed at a time. No frame numbers are displayed.
Motion Review	Displays CINE data in a continuous, forward direction. Reverse motion is not available.
Edit Start Edit End	Defines new beginning and ending points of a loop of CINE data.
Edit Reset	Resets the beginning and ending points to their originally acquired positions.
Align	Synchronizes the CINE display of the dual images during Dual mode.
Rate	Changes the speed of CINE review while in Motion Review.

## **Selections for 2D-Mode Measurements** and Calculations

WStenosis Perform a % stenosis calculation based on the area or diameter of the same vessel.  Perform a volume measurement in either two planes or one plane. Measurement methos available for calculating a volume in two planes are: LxDxW, Ellipse, and Trace.  Measurement methods available for calculating a volume in one plane are: LxD, Ellipse, and Disc.  Area Calculates the area using Ellipse or Trace method.  A/B Ratio Ratio of measurements. The system calculates the ratios A/B, B/A and (A-B)/A from the 2D-mode measurements: distance, area, or volume.  Angle Determines the angle using two lines you place on the image. The lines must connect or intersect.  Distance Simple linear measurement between two points.  Ellipse Ellipsical measurement. The system determines one diameter using the end points of the ellipse and calculates the second diameter.  Trace Free hand trace method. Roll the trackball to delineate an area. The system determines circumference and area using the trace segments.  2PI Trace Calculate volume by manually tracing structures in two planes.  Calculate a one-plane volume using the trackball to trace a structure and then positioning an axis line to be used for an assumed dimension in a second plane.  Calculate volume by measuring an ellipse in two planes.  Calculate volume by measuring and depth in one plane and width in a second plane.  Calculate volume by measuring length and depth in one plane and width in a second plane.	ne
available for calculating a volume in two planes are: LxDxW, Ellipse, and Trace.  Measurement methods available for calculating a volume in one plane are: LxD, Ellipse, and Disc.  Area Calculates the area using Ellipse or Trace method.  A/B Ratio Ratio of measurements. The system calculates the ratios A/B, B/A and (A-B)/A from the 2D-mode measurements: distance, area, or volume.  Angle Determines the angle using two lines you place on the image. The lines must connect or intersect.  Distance Simple linear measurement between two points.  Ellipse Elliptical measurement. The system determines one diameter using the end points of the ellipse and calculates the second diameter.  Trace Free hand trace method. Roll the trackball to delineate an area. The system determines circumference and area using the trace segments.  2PI Trace Calculate volume by manually tracing structures in two planes.  1PI Disk Calculate a one-plane volume using the trackball to trace a structure and then positioning an axis line to be used for an assumed dimension in a second plane.  2PI Ellipse Calculate volume by measuring an ellipse in two planes.  2PI LxDxW Calculate volume by measuring length and depth in one plane and width in a second plane.	ne
Area Calculates the area using Ellipse or Trace method.  A/B Ratio Ratio of measurements. The system calculates the ratios A/B, B/A and (A-B)/A from the 2D-mode measurements: distance, area, or volume.  Angle Determines the angle using two lines you place on the image. The lines must connect or intersect.  Distance Simple linear measurement between two points.  Elliptical measurement. The system determines one diameter using the end points of tellipse and calculates the second diameter.  Trace Free hand trace method. Roll the trackball to delineate an area. The system determines circumference and area using the trace segments.  2PI Trace Calculate volume by manually tracing structures in two planes.  1PI Disk Calculate a one-plane volume using the trackball to trace a structure and then positioning an axis line to be used for an assumed dimension in a second plane.  2PI Ellipse Calculate volume by measuring an ellipse in two planes.  Calculate volume by measuring length and depth in one plane and width in a second plane.	ne
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<b>2PI LxDxW</b> Calculate volume by measuring length and depth in one plane and width in a second plane.	g
ADI FILI	ne.
<b>1PI Ellipse</b> Calculate volume by measuring an area with an ellipse and identifying the axis commor both planes.	to
<b>1PI LxD</b> Calculate volume by measuring length and depth in one plane and assuming the same dimensions in the second plane.	
<b>Vol Ratio</b> Calculate ratios A/B, B/A, and (A-B)/A for volume.	
Area Ratio Calculate ratios A/B, B/A, and (A-B)/A for area.	
<b>Dist Ratio</b> Calculate ratios A/B, B/A, and (A-B)/A for distance.	
Trace Length Trace distance measurement between two points.	
A-% Stenosis Calculate area % stenosis, comparing cross-sectional areas of the same vessel.	
<b>D-% Stenosis</b> Calculate diameter % stenosis, comparing diameters of the same vessel.	
<b>Thyroid</b> Calculates thyroid volume.	
Residual Calculates a micturated volume by subtracting a post-void volume from a pre-void volume	ne.
<b>Incr Vol</b> <sup>1</sup> Calculates a volume of the prostate based on a series of area measurements.	
Note: Requires the Endo-P II transducer.	
Step Vol <sup>1</sup> Calculates a volume by adding areas of slices over a length.	
Note: Requires the Endo-P II transducer.	

<sup>&</sup>lt;sup>1</sup> Requires software version 2.0 or higher

# **Selections for M-Mode Measurements and Calculations**

Selection	Description
Velocity	Distance over time. The measurement is determined by two distance measurement markers.
Slope	Distance over time. The measurement is determined by two distance measurement markers.
Distance	Vertical distance between two points in the M-mode sweep.
A/B Ratio	Ratio of measurements. The ratios are A/B, B/A and (A-B)/A. Ratios can be determined for Distance, Heart Rate or Time measurements.
HR	Heart rate determined over one heart cycle in 2D/M-mode.
Time	Interval in seconds between two measurement markers.
Time Ratio	Calculate ratios A/B, B/A, and (A-B)/A for time.
Dist Ratio	Calculate ratios A/B, B/A, and (A-B)/A for distance.

# **Selections for All Measurements and Calculations**

When the Measurement function is active, you can access these selections by selecting **Other** from the top of the menu.

Selection	Description
Meas	Displays the Measured Results on the left of the screen.
Meas Pos	Specifies the position of the measurement.
Undo	Removes the last measurement from the screen and the report.
Modify	Activates the Modify feature for editing measurements.
Delete	Activates the Delete feature for removing measurements from the screen. The values of the removed measurements remain in the Measured Results and in the patient report.
Delete All	Removes all measurements from the screen. The values of the removed measurements remain in the Measured Results and in the patient report.

## **Biopsy/Puncture Selections**

For software versions 2.0 and higher: The **Biopsy** menu provides specific selections for the Endo-P II transducer.

[2] Instructions i	or Use
Biopsy Menu Selections for	
Endo-P II	Ch A4

Selection	Description
Reset Angle	Restores the original position of the biopsy/puncture guidelines.
Guide	Selects biopsy guidelines <b>On</b> or <b>Off</b> .
Angle Adjust	Finely adjusts the angle of the biopsy/puncture guidelines.
Dot Interval	Selects dot sizes to represent guidelines.
Display cm	Displays centimeter markings (numbers) indicating depth along the guidelines.

## Selections in DIMAQ-IP (Patient Data Management)

#### Study Screen • DIMAQ-IP

In the upper half of the Study screen, the system displays all studies that are saved on the currently selected disk in the **Disk** section of the screen. The columns displayed in the upper half of the screen include

Patient Name, Patient ID, Date/Time, Images, Clips<sup>1</sup>, Archived, and MBytes.

On the upper right of the Study screen, the system displays the utilized capacity and the total capacity of the selected disk (HD or CD). The system also displays the size of the selected studies (when multiple studies are selected).

On the upper left of the Study screen, the system indicates the number of studies displayed (and the total number of studies).

You can select multiple studies for export, import, or deletion.

In the CD section of the Study screen, the system indicates system recognition of the inserted CD (for example: **Ready**) and displays a graphic indicating used space on the CD. If the CD is inserted, then the system also displays a **Summary** sub-section (within the CD section) indicating the number of TIFF-formatted and DICOM-formatted images on the CD.

For software versions 2.0 and higher: The **Summary** sub-section (within the **CD** section) indicates the number of TIFF- and AVI-formatted images/clips and the number of DICOM-formatted items on the CD.

If the DICOM option is installed on the ultrasound system, then additional selections display on this screen.

Study Screen Selection	Description
Hide Studies	Limits the display of studies to those newer than the age selected in the drop-down list (for studies on hard disk only).
Change Screen	
Image Screen	Displays the Image screen with the images from the selected study.
Worklist Screen	(Requires the DICOM option)
	Displays the Worklist screen.
Procedure Screen	Reserved for future use.
Live Screen	Exits the Study screen and the Review function; redisplays the real-time imaging screen.
DICOM Screen	(Requires the DICOM option)
	Displays the DICOM screen.

**System Reference** 

DICOM selections Ch 6

<sup>&</sup>lt;sup>1</sup> Requires software version 2.0 or higher

Study Screen Selection	Description
Search for Studies	
Search	Displays a dialog box for entry of patient name, ID, and/or study date and then searches the currently selected disk for matching studies.
Show All	Displays all studies that are stored on the currently selected disk.
Disk	
HD	Lists studies on the system's hard disk.
CD	Lists studies on the inserted compact disk (CD).
CD	
Export	Copies the selected study from the system's hard disk to a CD. This selection is available when the <b>Disk</b> selection is <b>HD</b> , a CD is inserted, and a completed study is selected. The current study can also be selected.
Import	Copies the selected study from a CD to the system's hard disk. This selection is available when the <b>Disk</b> selection is <b>CD</b> , a CD is inserted, and a completed study is selected.
Eject	Ejects the CD.
Load	Closes the CD tray.
Finalize	Prevents additional storage to the currently inserted CD.
Export format (displayed for HD only)	Specifies the format(s) of exported images:
	<ul> <li>Tiff/AVI<sup>1</sup> exports images in the "Tagged Image File Format" (TIFF) format and clips in the AVI (audio-video interleave) format.</li> </ul>
	<ul> <li>TIFF<sup>2</sup> exports images in the "Tagged Image File Format" format.</li> </ul>
	<ul> <li>DICOM exports images in the DICOM (Digital Images and Communications in Medicine) format.</li> </ul>
	<b>Note:</b> DICOM-formatted data cannot be imported from CD to the system's hard disk. If you plan to import data that you are archiving onto a CD, then select the <b>Tiff/AVI</b> check box to archive Tiff-formatted images and AVI-formatted clips.
Study	
New	Creates a new study by re-registering the patient listed in the selected study. If a patient is already registered, the system first prompts you to close the current study.
Close	Closes the selected study.
Delete	Removes the selected study from the hard disk. Studies on a CD cannot be deleted using the DIMAQ-IP Study screen.
Network	
Send	(Requires the DICOM option)
	Copies the images from the selected study to the destination selected from the drop-down list.
(drop-down list)	Lists the available destinations (printer layout pages and storage servers).

<sup>&</sup>lt;sup>1</sup> Requires software version 2.0 or higher

<sup>&</sup>lt;sup>2</sup> For software versions below 2.0

**Note:** In this chapter, the term "Image screen" refers to a screen with the DIMAQ-IP option. In other chapters of the Operating Instructions, the use of "image screen" refers to a typical image screen that displays real-time images as they are acquired.

At the top of the Image screen, the system displays the Patient Name, Patient ID, and Date/Time of the study containing the displayed images.

For software versions below 2.0: Also at the top of the Image screen, the system indicates the current page number and the total number of pages (for example, "1/2" indicates that the system is displaying the first of two pages).

[2] Instructions for Use

Example of typical image screen Ch A2

**System Reference** 

DICOM selections Ch 6

If the DICOM option is installed on the ultrasound system, then additional selections display on this screen.

Image Screen Selection	Description	
Slideshow <sup>1</sup>	Enables automatic sequential viewing of images.	
1 x 1, 2 x 2, 3 x 3,	Changes the layout format (number of images per page) to the selected number.	
<b>4 x 4, 5 x 5</b> (drop-down list)	<b>Note: 5 x 5</b> is not available for software versions below 2.0.	
A	When enabled (checked), locks the selected layout format until system shutdown.	
	When disabled (unchecked), the system optimizes the display format to fit the number of images contained in the selected study onto one page.	
BW Print	(Requires the DICOM option)	
	Sends the selected image to the DICOM BW Printer Layout page.	
Delete	Removes the selected image from storage.	
Options <sup>2</sup>	Accesses a dialog box for enabling simultaneous clip playback and configuring sequential viewing (slide show capability).	
Clip Speed <sup>2</sup>	Adjusts the playback speed of all clips in the selected study.	
Close Study	Completes the current patient examination and displays the Study screen.	
Procedure Screen <sup>2</sup>	(Requires the DICOM option)	
	Displays the <b>Choose procedure</b> screen for selection of another procedure for the currently registered patient.	
Study Screen	Displays the Study screen.	
Live Screen	Exits the Image screen and the Review function; redisplays the real-time imaging screen.	
DICOM Screen	(Requires the DICOM option)	
	Displays the DICOM screen.	
Previous	Displays the previous page of images and automatically selects the last image on that page.	
Next	Displays the next page of images and automatically selects the first image on that page.	

 $<sup>^{\</sup>mathrm{1}}$  For software versions below 2.0

<sup>&</sup>lt;sup>2</sup> Requires software version 2.0 or higher

Image Screen Selection	Description
1	Displays the first frame of the selected clip.
	Displays the previous frame of the selected clip.
1	Stops playback of the clip.
1	Starts playback of the clip.
<b>&gt;&gt;</b>	Displays the next frame of the selected clip.

## **Options Dialog Box**

(Requires software version 2.0 or higher)

The system displays the **Options** dialog box when you select **Options** from the Image screen.

In the table below, titles of sections are indicated in brackets ([]).

Selection	Description	
[Clip Playback]		
Play Only Selected Clip	Disables simultaneous playback of all clips in the currently displayed study.	
Play All Clips	Enables simultaneous playback of all clips in the currently displayed study.	
[Slideshow]		
Slideshow on	Configures clips and images for sequential viewing in the currently displayed study.	
Image Period (sec)	Specifies the length of display for each image.	
Clip Play Loops	Specifies the number of times each clip is played back.	

-

<sup>&</sup>lt;sup>1</sup> Requires software version 2.0 or higher

## **DICOM Screen Selections**

The following descriptions for the Study, Image, and DICOM screens are specific to the DICOM Connectivity option. DIMAQ-IP Study and Image screen selections are also available for use with this option.

**System Reference** Study screen Ch 4 Image screen Ch 4

In the **Network** section of the Study screen, the system indicates the connection status (for example: **Ping OK**).

## **Study Screen**

Study Screen Selections	Description
Change Screen	
DICOM Screen	Displays the DICOM screen for access to printer layout pages and print and store queues.
Worklist Screen	Displays the <b>Worklist Search</b> screen to select a scheduled procedure for either a new study or the current study (different accession number).
	<b>Note:</b> This selection is available when the Worklist option is installed and the Worklist server is configured.
Procedure Screen <sup>1</sup>	Displays the <b>Choose procedure</b> screen to select a scheduled procedure for the current study (same accession number).
	<b>Note:</b> This selection is available when a connected Worklist server contains multiple procedures (same accession number) for the current study.
Network	
Send	Copies the images from the selected study to the destination selected from the drop-down list.
(drop-down list)	Lists the available destinations (printer layout pages and storage servers).

<sup>&</sup>lt;sup>1</sup> Requires software version 2.0 or higher

## **Image Screen**

On the left of the Image screen, the system indicates the number of images on the printer layout page and the number of images required to fill the page. For example, "1/4" indicates that one image has been sent to the printer layout page and that four images are required to fill the layout page.

Image Screen Selections	Description
BW Print	Sends the selected image to the <b>DICOM BW Printer Layout</b> page.

#### **DICOM Screen**

The DICOM screen displays layout pages for the black and white printers and queue status pages for the DICOM print and store functions.

## **Printer Layout Pages**

The system displays the **DICOM BW Printer Layout** page tab at the top of the DICOM screen. The selections available for the printer layout pages are described below. The system also lists the following settings at the top of each page: setup alias, film size, number of copies, and film orientation (Portrait or Landscape); these settings are only selectable in the system presets.

#### **System Reference** System Presets Ch 3 F6 DICOM ▶ Black and White Printer

Selection	Description
Delete	Removes the outlined image from the layout page.
Cut	Marks the outlined image for rearranging.
Paste	Inserts the cut image in place of the paste image.
1x1 1x2 2x2 2x3 3x2 3x3 3x5 4x5 4x6 5x6	Identifies the columns and rows needed to assemble a full page of print images. This setting ( <b>Display Layout</b> ) is selected separately in the system presets for each type of printer and cannot be changed from a layout page.
Print Page	Sends the current page of images to the <b>DICOM Print Queue</b> . The <b>Display Layout</b> requirements do not need to be filled to print the page.
Print All Pages	Sends all pages of images to the <b>DICOM Print Queue</b> .
Back	Displays the Study screen.
Change	Displays a dialog box for change of printer selection, film size, number of copies, and print orientation.
Previous	Displays the preceding page of print images. Not available if no preceding page exists.
Next	Displays the next page of print images. Not available if no following page exists.
1/2	Identifies the active page over the total number of pages.

#### **Print and Store Queues**

Page tabs displayed along the top of the DICOM screen include:

- DICOM Print Queue
- DICOM Store Queue

The system lists the following items for each entry in the DICOM Print Queue:

- Patient Name
- Printer
- Time Sent
- No of Copies
- No of Sheets
- Status
- Details<sup>1</sup>, Errors Details<sup>2</sup>

The system lists the following items for each entry in the DICOM Store Queue:

- Type
- Patient Name
- Server
- Time Sent
- MBytes
- State
- Status
- Details<sup>1</sup>, Errors Details<sup>2</sup>

The selections available for the print and store queue status pages are described below.

Selection	Description
Back	Displays the Study screen.
Refresh Queue <sup>2</sup>	Updates the status of each entry in the queue.
Retry Job	Attempts to resend the selected queue entry.
Delete Job	Deletes the highlighted queue entry.
	You can select and delete multiple queue entries.

#### **System Reference**

System Presets Ch 3



F6

DICOM

▶ Black and
White Printer

► ► Write Timeout in Seconds

<sup>&</sup>lt;sup>1</sup> Requires software version 2.0 or higher

<sup>&</sup>lt;sup>2</sup> For software versions below 2.0

## 4 System Setup

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4 System Setup

## **Initial Setup**

After your ultrasound imaging system is initially unpacked and installed, including any transducers and system options, such as the black and white printer or footswitch, you must verify system operation.

#### **System Reference**

Printer Installation Ch 5

Note: The monitor filter option includes an installation procedure.

Each day before you use the ultrasound system, perform the Daily Checklist procedures described below.

### **Daily Checklist**

#### Perform the following each day before using the ultrasound system:

☐ Visually inspect all transducers. Do not use a transducer with a cracked, punctured, or discolored casing, or a frayed cable.

**Discoloration Exception:** The use of Cidex OPA and Gigasept FF disinfectants may cause discoloration of transducer housings. You can continue to use a transducer if it is discolored due to the use of these specific disinfectants only.

☐ Visually inspect all power cords. Do not turn on the power if a cord is frayed or split, or shows signs of wear.

If your system's power cord is frayed or split, or shows signs of wear, contact your Siemens service representative for power cord replacement.

☐ Verify that the trackball, DGC slide controls, and other controls on the control panel are clean and free from gel or other contaminants.

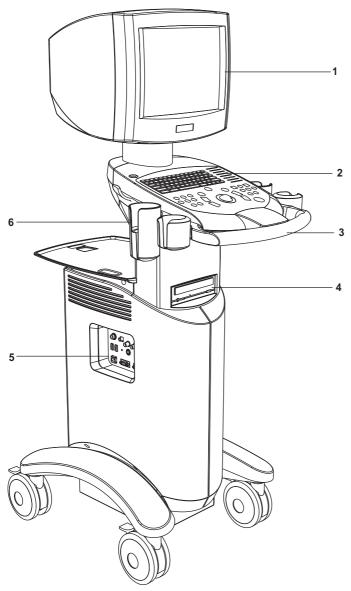
#### Once the system is powered on:

- ☐ Visually check the on-screen displays and lighting.
- ☐ Verify that the monitor displays the current date and time.
- Verify that the transducer identification and indicated frequency are correct for the active transducer.

#### [1] Instructions for Use

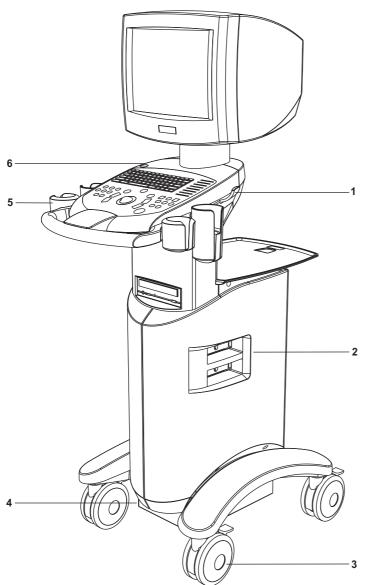
Approved List of Disinfectants Ch 2

## **System Review**



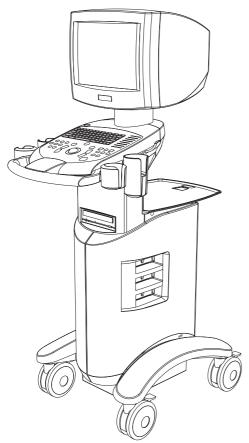
Example of the ultrasound system, left front view.

- 1 User-adjustable monitor
- 2 Back-lit control panel with alphanumeric keyboard
- 3 Front handle
- 4 Compact Disk (CD R/W) drive
- 5 Input/Output panel
- 6 Transducer and gel holders

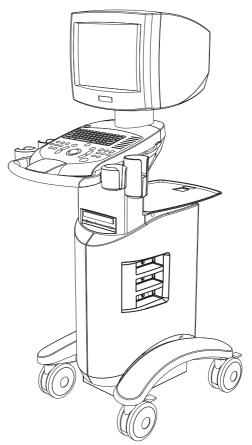


- 1 Transducer cable hanger
- 2 Transducer ports
- 3 Swivel wheel with brake
- 4 Air filter
- 5 Transducer holders
- 6 Power (partial) on/off ( $^{\circ}$ ) switch

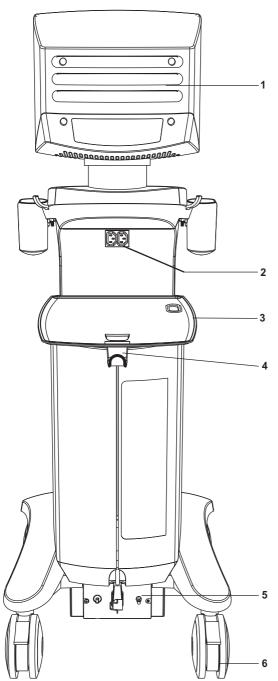
Example of the ultrasound system, with standard array transducer ports, right front view.



Example of the ultrasound system, with standard array transducer ports and a standard array parking port right front view.



Example of the ultrasound system, with standard array transducer ports and a mechanical sector transducer port right front view.



Example of the ultrasound system, back view.

- 1 Monitor
- 2 Accessory outlet panel
- 3 Shelf
- 4 Cable holder
- 5 Power panel with circuit breaker
- 6 Swivel wheel with brake

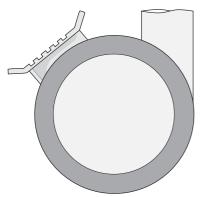
△ Caution: Preparations before moving the system are important to minimize potential damage to sensitive components and to avoid safety hazards. Review the moving instructions before moving the system.

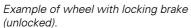
△ Caution: Do not park, or leave unattended, on a slope. Even when the rear brakes are engaged, the system may slide down a ramp.

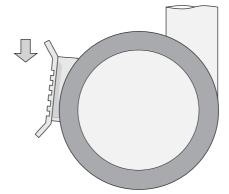
The ultrasound system is designed to be a mobile unit. Before moving the system to another location, you must prepare for the move by powering off and securing the system.

## **Swivel Locking Brake**

The ultrasound system has four swivel locking brakes.







Example of wheel with locking brake (locked).

#### To lock each wheel:

 Using your foot, push down on the lever (toward the "LOCK" label) to lock the brake and swivel.

#### To release the brake on each wheel:

 Using your foot, push up on the lever (toward the "FREE" label) to release the brake and swivel.

## **Prior to the Move**

- 1. Power off (b) the ultrasound system.
- 2. Unplug the power cord from the wall outlet. Pull on the plug, not the cord.
- 3. Secure the power cord to avoid rolling the system wheels over the cord.
- 4. To ensure that the transducers are transported safely, remove each transducer and place it in its protective carrying case.
- 5. Unplug any connections from the system's input/output panel. These connections include network cables, peripheral devices (such as off-board documentation devices), and the optional footswitch.
- 6. Transport accessories (such as gel and CD-R disks) separately.
- 7. Release both the front and rear brakes.

# **During the Move**

⚠ **Caution:** When moving the ultrasound system, protect it from environmental changes including: moisture, winds, dirt and dust, and extreme heat or cold exposure.

Power Off 4-13
Transducer Care Ch 2

△ Caution: Avoid moving the ultrasound system on outside surfaces with loose dirt, contaminates, or standing liquids.

△ Caution: Care should be taken to minimize shock and vibration of the ultrasound system. Avoid uneven surfaces that contain an abrupt height change or jarring surface irregularities.

You can move the ultrasound system from room to room within a facility and easily reposition the system during an examination. Be careful on inclines and uneven surfaces. The ultrasound system can be moved across pavement and other hardened parking lot surfaces.

**Note:** The wheels of the ultrasound system must be locked when transporting by vehicle. The ultrasound system must be sufficiently anchored to the vehicle floor or walls such that it does not shift or move during transport.

# **Shipping the System**

When shipping the system, perform the following tasks, as appropriate.

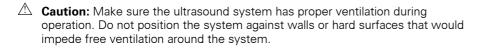
## To prepare the system for shipment over long distances or rough terrain:

- 1. Repack the system in the factory packaging and crate.
- 2. Load the system into a vehicle using a lift gate.

To prevent lateral movement of the system, secure the system with cargo straps.

To prevent sudden jarring of the system during transport, provide shock cushions beneath the system.

## After the Move



△ Caution: Do not allow linens, bedding, and/or hanging curtain partitions to block the ultrasound system's ventilation.

△ Caution: Obstructed fans can cause potential system overheating, system performance degradation, or failure.

Caution: Brakes are most effective on a level surface. Never park the system on an incline greater than five degrees.

- 1. Position the system: Make sure the system is not placed against walls or fabrics that obstruct perimeter air flow to the system cooling fans.
- 2. Lock the front and rear brakes.
- 3. Plug in the cord: Plug the power cord into a hospital-grade or local equivalent wall outlet.
- 4. Power ON: Power on (Φ) the ultrasound system.
- 5. Check the display: After the boot-up sequence is complete, verify that the image display is stable, that you can select a transducer, and that the system responds to selections made on the control panel.

#### [1] Instructions for Use Daily Checklist 4-3

4-9

Brakes

# **System Startup**

The first step to operating the ultrasound system is to connect the system to a power source.

[1] Instructions for Use

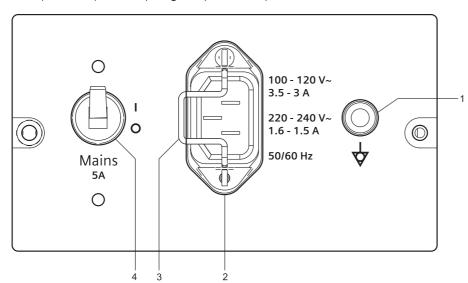
Power Supply Requirements Ch 6

**Note:** The ultrasound system has a universal power supply to support 100V $\sim$ , 115V $\sim$ , and 230V $\sim$  mains voltage.

# Plugging in the System

The ultrasound system has a detachable power cord.

⚠ **WARNING:** For 115V units only: to ensure grounding reliability, connect the system only to a hospital-grade power receptacle.



- 1 Equipotential connector
- 2 Power cord connector
- 3 Safety Lock
- 4 MAINS circuit breaker I = on O = off

Example of power panel.

## To plug in the system:

1. On initial system setup, select and connect the power cord and safety lock to your ultrasound system according to the installation instructions enclosed with the system shipment.

Package Label	Power Cord Type	
E-type	230V~	
A-type	115V~, 100V~	

2. Plug the ultrasound system's power cord into the power source (wall outlet).

Ultrasound System's Universal Power Supply	Power Source
230V~	230V standard mains, i.e. "Schuko" receptacle (CEE 7-7 standard)
115V~	Hospital-grade MAINS receptacle
100V~	Standard 100V MAINS receptacle

# **Supplying Power to the System**

The ultrasound system is powered on and off using the partial power on/off (0) switch located on the upper left of the keyboard. This switch glows blue when the system's power is on and amber when the system's power is standby.

**Note:** This switch does not completely shut down or disconnect the system from the power mains. This switch only powers on, or off, a portion of the ultrasound system. To completely disconnect the system from the power mains, the circuit breaker located on the back panel must be switched from **I** to **O**.

△ Caution: Wait approximately 20 seconds between powering the system off and then on again. This allows the system to complete its shutdown sequence.

## To power on the system:

- 1. Before using the system, perform the Daily Checklist.
- 2. Verify the power cord is plugged into the system and then into the power supply.
- 3. Power on ( $\circlearrowleft$ ) the ultrasound system.

When powered on, the system runs through a series of self-diagnostic and calibration tests. The tests last approximately one minute, after which the system is ready for use.

**Note:** The system will not run through the complete power-on routine if a problem occurs. Instead, an error code or message appears on the screen to indicate the problem. Please note the message and call your local Siemens service representative.

The system is factory-configured to display initially in 2D-mode.

4. Visually check the on-screen displays and lighting indicated in the Daily Checklist.

#### To power off the system:

**Note:** Always close dialog boxes and related error message and confirmation dialog boxes prior to powering off the system. This action will prevent excessive power off periods.

1. Press the power on/off ( $\phi$ ) switch located on the upper left of the control panel.

The system displays a confirmation message.

2. Select  $\mathbf{OK}$  or press the power on/off ( $\circlearrowleft$ ) switch again.

Wait approximately 20 seconds before powering on the ultrasound system.

#### [1] Instructions for Use

Daily Checklist 4-3

# **Adjusting Controls on the Monitor**

The brightness control  $(\diamondsuit)$  and the contrast control  $(\bullet)$  are located under the left, front edge of the monitor.

**Note:** Factory-defined imaging presets were created using default settings of the brightness and contrast controls of the monitor. Adjusting the brightness and contrast controls on the monitor may affect the image optimization intended by the factory-defined imaging presets.

For consistency in image reproduction, adjustments to the brightness and contrast of the viewing monitor should be made prior to adjusting the print quality of installed documentation devices.

### To adjust the brightness or contrast control for the monitor:

**Note:** Always begin adjusting your monitor with the controls set to the factory defaults, and then adjust each control separately to suit your preference and the lighting conditions in the room.

- Rotate the brightness control (🌣) clockwise for a brighter image with a lighter background. Rotate the brightness control counterclockwise for a darker image.
- Rotate the contrast control (①) clockwise to increase the display contrast. Rotate the contrast control counterclockwise to decrease the display contrast.

# To restore the factory default monitor settings for brightness and contrast:

- 1. Rotate the brightness control (菜) to the center (detent) position.
  The system restores the factory default setting for brightness.
- 2. Rotate the contrast control (①) to the center (detent) position. The system restores the factory default setting for contrast.

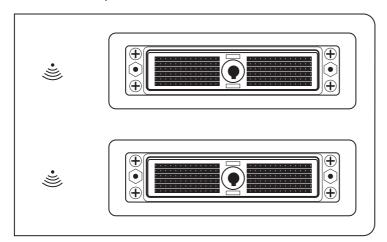
# **Connecting and Disconnecting Transducers**

△ Caution: Ensure that the system is in freeze before connecting and disconnecting transducers. If a transducer is disconnected before the image is frozen, the system will display an error message, and it will be necessary to reset the system before continued use.

You can connect multiple transducers to the ultrasound system, with one transducer being the *active* transducer.

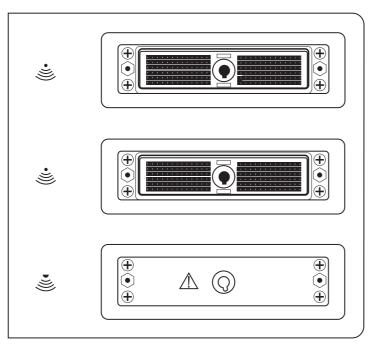
## System configurations:

- Two standard array transducer ports
- Two standard array transducer ports and one mechanical sector transducer port<sup>1</sup>
- Two standard array transducer ports and one parking port for linear and curved array transducers

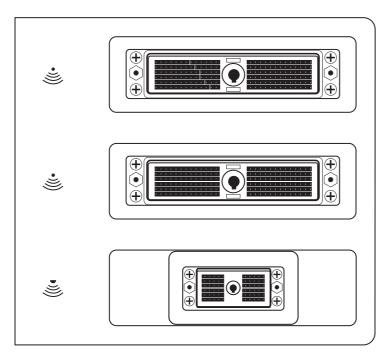


Example of standard array transducer ports.

<sup>&</sup>lt;sup>1</sup> Requires software version 2.0 and higher



Example of standard array transducer ports and a standard array parking port.



Example of standard array transducer ports and a mechanical sector port.

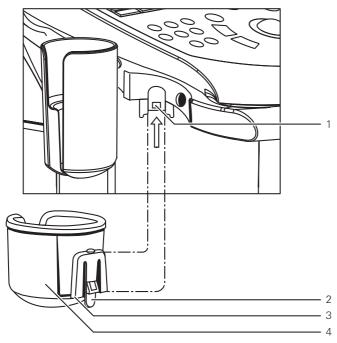
## **Protective Transducer Holder**

△ Caution: Transducer holders have variable sizes, both in depth and diameter. To avoid transducer damage, you must use the holder or insert provided for transducers that have small or large diameter handles or for specialty transducers, such as endocavity transducers.

After connecting a transducer to the system, place the transducer in the protective holder attached to the control panel platform. A holder can also be used for the coupling agent (gel).

## **Transducer Holders**

The transducer holders on the sides of the control panel are interchangeable and replaceable.



Example of transducer holders.

- 1 Point of attachment
- Tab
- 3 Support
- 4 Holder

#### To remove a transducer holder:

- 1. Reach under the holder to locate the tab on the holder.
  - The tab extends below the point of attachment to the ultrasound system.
- 2. Squeeze the tab towards the holder and pull the holder downward.

#### To install a transducer holder:

 Align the support on the holder directly below the point of attachment on the ultrasound system and firmly push upwards until the holder snaps into place.

#### To assemble a transducer holder with an extension:

 Align the tabs on the transducer holder with the slots on the extension and push together until the extension snaps into place.

You can now install the transducer holder onto the ultrasound system.

#### To disassemble a transducer holder with an extension:

 Squeeze the tabs on the side of the transducer holder and pull the extension away from the transducer holder.

## **Transducer Cable Management**

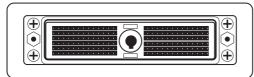
After you have connected and secured a transducer, drape the transducer cable through one of the cable hangers located on the sides of the ultrasound system. These hangers provide support for the transducer cables, keep cables off the floor, and help to prevent tangling of the cables when more than one transducer is connected to the system.

# **Array Transducers**

△ Caution: You must freeze the system before connecting or disconnecting a transducer.

Note: When transducer connectors are being attached to or disconnected from the system, resistance may be encountered due to the special shielding material inside the connectors. This is normal for these transducers.





Array transducer port.

#### To connect an array transducer:

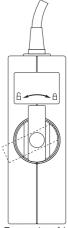
1. Insert the connector pins into the system port. Adjust the connector until you can turn the lever on the transducer connector clockwise to lock it in position.

This secures the connector in position and ensures the best possible contact.

2. Place the transducer in the transducer holder and drape the cable through the cable hangers.

## To disconnect an array transducer:

- △ Caution: To avoid damaging the transducer cable, do not pull on the cable to disconnect the transducer. Use the following instructions.
- 1. Turn the lock on the connector housing counterclockwise until
- 2. Firmly grasp the transducer connector and carefully remove it from the system port.
- 3. Store each transducer in its protective carrying case.



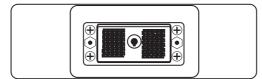
Example of locked and unlocked positions of the connector.

## **Mechanical Sector Transducers**

Ultrasound systems for use with linear array, convex array, and mechanical sector transducers have a mechanical sector transducer port.

**Note:** When transducer connectors are being attached to or disconnected from the system, resistance may be encountered due to the special shielding material inside the connectors. This is normal for these transducers.





Mechanical sector transducer port.

#### To connect a mechanical sector transducer:

1. Insert the connector pins into the system port. Adjust the connector until you can turn the lever on the transducer connector clockwise to lock it in position.

This secures the connector in position and ensures the best possible contact.

2. Place the transducer in the transducer holder and drape the cable through the cable hangers.

#### To disconnect a mechanical sector transducer:

- ⚠ **Caution:** To avoid damaging the transducer cable, do not pull on the cable to disconnect the transducer. Use the following instructions.
- 1. Turn the lock on the connector housing counterclockwise until it unlocks.
- 2. Firmly grasp the transducer connector and carefully remove it from the system port.
- 3. Store each transducer in its protective carrying case.



Example of locked and unlocked positions of the connector.

# **Connecting System Accessories**

# **Footswitch**

The ultrasound system has an optional dual-pedal, watertight footswitch.

## To connect the footswitch to the system:

 Insert the footswitch connector housing into the socket located on the input/output panel.





Footswitch label identifying the connector socket.

## **Input/Output Panel Connections**

Video and communication connections are on the input/output panel. The input/output panel is located on the left side of the ultrasound system.

MARNING: Accessory equipment connected to the analog and digital interfaces must be certified according to the respective EN and IEC standards (for example, EN 60950 and IEC  $609\bar{5}0$  for data processing equipment and EN 60601-1 and IEC 60601-1 for medical equipment). Furthermore, all configurations shall comply with the system standards EN 60601-1-1 and IEC 60601-1-1. Anyone who connects additional equipment to any signal input or signal output ports configures a medical system and is therefore responsible that the system complies with the requirements of the system standards EN 60601-1-1 and IEC 60601-1-1. Siemens can only guarantee the performance and safety of the devices listed in the System Reference. If in doubt, consult the Siemens service department or your local Siemens representative.

# 0 0 0 0 $\triangle \Diamond$ Ó $\bigcap \Theta$ USB 2 10 3 VGA O \_\_\_\_\_ RS-232-C (Y/C) **()** (√) 9 6 5

- Input/output panel connections.
- Video Out
- Printer Control connection (remote control
- Video In (composite)
- Footswitch
- 5 S-Video In
- 6 Video Out (VGA)

- S-Video Out
- Serial Port
- **Ethernet Connection**
- 10 USB Ports
- 11 Status Indicators (for service diagnostics only)

The impedance of the video input to the ultrasound system must be matched to the output impedance of the peripheral device using system presets. Standard video devices have an output impedance of 75 ohms, so the video impedance is normally set to 75-ohm.



F6

Peripheral

► Video Input Impedance

**System Reference** 

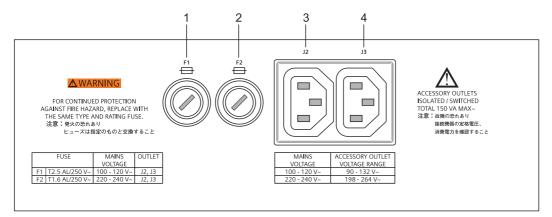
Ch 2

Accessories

and Options

# **Accessory Outlet Panel**

The accessory outlet panel is located above the shelf on the back of the system. The panel has two isolated outlets (J2 and J3) and associated fuses. Both outlets are protected by fuse F1 when the Mains voltage is from  $100V \sim to 120V \sim$ ; by fuse F2 when the Mains voltage is from  $220V \sim to 240V \sim$ .



Accessory outlet panel.

- 1 Fuse F1 (100V~ to 120V~)
- 2 Fuse F2 (220V~ to 240V~)
- 3 Accessory outlet J2
- 4 Accessory outlet J3

## **Connecting Peripheral Equipment**

In order to fulfill EN 60601-1-1 and IEC 60601-1-1 (Medical Electrical Equipment, Part 1: General Requirements for Safety) requirements, connection of peripheral equipment to your ultrasound imaging system must adhere to one of the following conditions:

- The peripheral equipment itself is a medical device approved according to EN 60601-1 and IEC 60601-1, or
- Non-medical peripheral equipment approved according to any other EN or IEC standard (EN XXXXX or IEC XXXXX, e.g., equipment complying with EN 60348 and IEC 60348, EN 60950 and IEC 60950, etc.) must use the following setup for connection:
  - Connect the imaging system to an independent protective earth terminal, with a ground wire connection to the ultrasound systems equipotential connector. Ensure that the protective earth wire is connected to a qualified protective earth connection independent of the existing systems earth connection (via the power cable).
  - The peripheral equipment is located at least 1.5 meters (1.8 meters [6 feet] in Canada and the U.S.A.) outside of the patient environment. A patient environment is defined as the area in which medical examination, monitoring, or treatment of the patient takes place.
  - The peripheral equipment is connected to a main outlet outside the patient environment but still within the same room as the imaging system.

For additional information and other possible combinations, please refer to the Medical Electrical Equipment Standard EN 60601-1-1 or IEC 60601-1-1, Annex BBB.7, Scenario 3c.

**Note:** The above information is based on current EN 60601-1-1 and IEC 60601-1-1 standards, dated 2000-12. If your country's regulatory standards for medical equipment do not correspond to EN 60601-1 and IEC 60601-1 as well as EN 60601-1-1 and IEC 60601-1-1, your local requirements may be different.

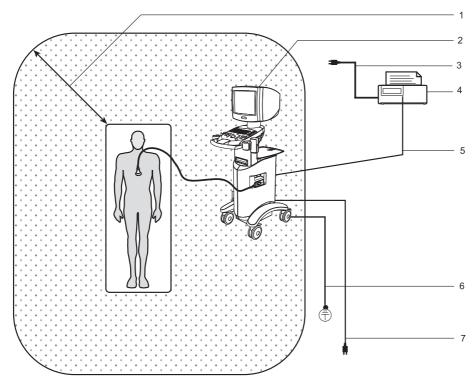
#### **System Reference**

Report Printers

Ch 5



Equipotential connector located on power panel of imaging system.



Example of a Peripheral Equipment Connection and Patient Environment.

- 1 Patient environment (represented by dot pattern, extending exactly 1.5 meters (1.8 meters [6 feet] in Canada and the U.S.A.) around patient and ultrasound system)
- 2 Ultrasound system
- 3 Peripheral equipment power
- 4 Peripheral equipment (EN XXXXX and IEC XXXXX)
- 5 RS-232C cable or video in/out
- 6 Additional Protective Earth (refer to 4-24)
- 7 Ultrasound system power

#### **Serial Port**

The system has a serial port for connecting to a PC or to a serial printer.

## **Configuring the Serial Port**

Use the system presets to select the destination for data sent through the serial port on the ultrasound system.



Peripheral

► External RS-232C Port



△ Caution: Should you disconnect the RS-232C cable from peripheral equipment, always connect the termination cap to the cable connector. The termination cap protects the pins on the connector and protects the system from potential image degradation due to radio wave interference.

# **Configuring the Documentation Controls**

You can configure the documentation controls for printing, storing, and/or the TGO tissue grayscale optimization optional feature.

System Reference
System Presets Ch 3

For software versions 2.0 and higher: You can also configure documentation controls for storing clips.

Use the system presets to configure clip options (such as length).

# F6 Clip Capture

## To configure the documentation controls:

- 1. Press the **F6** key on the keyboard to access the system presets.
  - The system displays the **Preset Main Menu** screen.
- 2. Select **Customize Keys** on the left of the screen.
- 3. For each documentation control (**PRINT STORE**, **DIGITAL STORE 1**, or **DIGITAL STORE 2**), select the required option:

To configure the documentation control for:	Select this option:
Storage to the hard disk	Disk Store
Printing to the black and white printer	B/W Print
Printing to the DICOM black and white printer	<b>DICOM B/W Printer</b>
Storage to the hard disk and printing to the black and white printer	D. Store and B/W Pr.
Optimization of tissue grayscale (TGO feature)	TGO
<b>Note:</b> TGO is not available for the <b>PRINT STORE</b> key.	
For software versions 2.0 and higher: Stores clips	Clip Capture
<b>Note:</b> This option is not available for the <b>PRINT STORE</b> key.	

4. Select the **Save** button to store the new settings and exit the system presets.

# **General System Settings**

You can change general system settings such as the on-screen display of the date, time, and hospital name using the system presets. These settings display on the image screen as well as on patient reports.

**Note:** If the setup menus are accessed when the system is in freeze, you must unfreeze the system to display the changes.

#### **System Reference**

System Presets

Ch 3

# **Modifying Hospital or Clinic Name**

To change the hospital or clinic name, enter a new name into the system preset.

## ≣ F6

## \_

General ► Hospital Name

## To change the hospital name:

- Press the F6 key on the keyboard to access the system presets.
   The system displays the Preset Main Menu screen.
- 2. Roll the trackball to **General** on the left of the screen and then press the **SET** key on the control panel.
- 3. Roll the trackball to **Hospital Name**, and then press the **SET** key.
- 4. Enter a name and then press the **SET** key. You can enter up to 60 characters.
- 5. Roll the trackball to **Save** and then press the **SET** key to store the new settings and exit the system presets.

# **Setting System Date and Time**

The date is displayed numerically on the upper right of the image screen. You can change the system date and format and time, including time zone and daylight savings time correction.

**Note:** To view your changes to the image screen, unfreeze the system.

#### To select the date format:

- Press the F6 key on the keyboard to access the system presets.
   The system displays the Preset Main Menu screen.
- 2. Roll the trackball to **General** on the left of the screen.
- 3. Roll the trackball to Month/Day/Year, Day/Month/Year, or Year/Month/Day in the Date Format area, then press the SET key on the control panel.
- 4. Roll the trackball to **Save** and then press the **SET** key to store the new settings and exit the system presets.

### To change the system date:

- Press the F6 key on the keyboard to access the system presets.
   The system displays the Preset Main Menu screen.
- 2. Roll the trackball to **Day / Time** and then press the **SET** key.
- 3. Enter the date by completing the **Month**, **Day**, and **Year** fields. For example, to enter March 20, 2005 in the *Month*, *Day*, *Year* format, enter 03 for the month, 20 for the day, and 2005 for the year.
  - Use the **TAB** key to advance to the next field. Use the trackball to reposition the text cursor if you need to make a correction.
- 4. Activate the new settings by rolling the trackball to the **Set** button to the right of these fields and pressing the **SET** key on the control panel.

#### **System Reference**

System Presets

Ch 3



го

▶Time

General

▶ Date format
Day / Time

▶ Date

## To change the system time:

- Press the F6 key on the keyboard to access the system presets.
   The system displays the Preset Main Menu screen.
- 2. Roll the trackball to **Day / Time** and then press the **SET** key.
- 3. Enter the time by completing the **Hour**, **Minute**, and **Second** fields.
  - Use the **TAB** key to advance to the next field. Use the trackball to reposition the text cursor if you need to make a correction.
- 4. Activate the new settings by rolling the trackball to the **Set** button to the right of these fields and pressing the **SET** key on the control panel.
- To adjust the time for Daylight Savings, roll the trackball to the Daylight Savings Time Adjustment (+1 Hour) check box and then press the SET key.
- 6. To set the time zone, roll the trackball to the **Time Zone** drop-down list and then press the **SET** key.
  - a. Using the **SET** key, scroll up or down the list until the required time zone appears.
  - b. Roll the trackball to highlight the required time zone and then press the **SET** key.
- 7. Roll the trackball to the **Save** button and then press the **SET** key on the control panel.

# **Software Installation**

You can install a software upgrade or you can reload existing software; you can also re-install the operating system (OS) on the ultrasound system. Before starting a software installation, back up user-defined settings, and the patient database, and uninstall key disk options.

# **Loading System Software**

Prerequisite: If you plan to delete user-defined settings during software installation (by selecting Initialize Preset on the System/Language screen), then Siemens recommends that you make a back-up copy of user-defined settings (system presets, QuickSets, and OB tables and formulas) before beginning this procedure.

## To load new system software or reload system software:

- 1. With the system powered on, insert the System Disk into the CD drive.
  - Press the eject button on the right of the CD drive, which is located below the control panel on the front of the ultrasound system.
  - b. Insert the System Disk into the CD tray and press the eject button to close the CD tray.
- 2. Press the **F6** key on the keyboard to access the system presets.

The system displays the Preset Main Menu screen.

3. Select **System/Language** on the left of the screen, and then select one of the following selections:

Note: System/Language may appear on the second page of the Presets Main Menu. To see the second page of the menu, roll the trackball to the down arrow at the bottom of the menu and press the **SET** key on the control panel.

- Select **Retain Current Preset** to retain user-defined settings (system presets, QuickSets, OB tables and formulas) and retain the current language selection.
- Select Initialize Preset to delete user-defined settings (system presets, QuickSets, OB tables and formulas) and reset the language selection to the factory default. **Initialize Presets** also removes key disk options.

Note: Siemens recommends that you retain user-defined settings. If you select Initialize Presets, then make a backup copy of user-defined settings (system presets, QuickSets, and OB tables and formulas) before deleting user-defined settings.

#### [1] Instructions for Use

Software-Based Option Installation 4-34

#### [2] Instructions for Use

QuickSets

#### **System Reference**

Saving Patient Data Ch 4 Compact Disk Drive Ch 5 Storing

System Presets Ch 5

## System Reference

Compact Disk Drive Ch 5 Storing

System Presets Ch 5

4. Select the **Upgrade System** button to begin software installation.

The software installation process takes approximately five minutes.

When the installation process completes, the system displays a message indicating the install was successful prompts you to power off the system.

- 5. Press the eject button on the CD drive and remove the System Disk.
- 6. Roll the trackball to the **Shut Down** button in the message and press the **SET** key.

The system screen goes dark and powers off. Wait 20 seconds before powering on the system.

**Note:** If you selected **Initialize Preset** during this procedure, the system language may change. Use the system presets to select another language. To change the language, press the **F6** key, select the down arrow at the bottom of the left side of the screen, select **System/Language** on the left of the **Preset Main Menu**, select another language, and then select the **Change Language** button. Wait for the system to power off and then press the power on/off switch to power on the system.

Ch 3

System Reference

System Presets

- 7. Press the power on/off ( $^{\circ}$ ) switch located on the upper left of the control panel to power on the system.
- 8. To confirm the software installation:
  - a. Press **F6** to display the **Preset Main Menu**.
  - b. Select Service.
  - Confirm that the version of the system host software listed in the Product SW version matches the version of software from the System Disk.
  - d. Select Cancel to exit the service login window.
- 9. If you un-installed key disk options or initialized presets, then reinstall the key disk options.

#### [1] Instructions for Use

Supplying Power to the System 4-13

[1] Instructions for Use

Software-Based Option Installation 4-34

## **OS-System Disk**

OS-System Disk. The OS-System Disk overwrites the ultrasound system's hard drive. Before you upgrade the software, back up preset and patient data, and uninstall key disk options.

The OS-System disk is an auto bootable CD. If inserted in the CD drive, then the disk will overwrite the local hard drive while cycling power to the ultrasound system.

#### System Reference

Saving Patient Data Ch 4 Compact Disk Drive Ch 5 Storing System Presets

#### [1] Instructions for Use

Software-Based Option Installation 4-34

## To load system software and DIMAQ software using the OS-System Disk:

- 1. With the system powered on, insert the OS-System Disk into the CD drive.
  - Press the eject button on the right of the CD drive, which is located below the control panel on the front of the ultrasound system.
  - b. Insert the OS-System Disk into the CD tray and press the eject button to close the CD tray.
- 2. Press the power on/off (b) switch located on the upper left of the control panel to power off the system. The system displays a confirmation message.
- 3. Select **OK** or press the power on/off ( $\circlearrowleft$ ) switch again.

The system screen goes dark and powers off. Wait 20 seconds before powering on the system.

4. Press the power on/off (0) switch to power on the system.

The system displays an "R" prompt on the image screen in approximately five minutes.

- 5. Remove the OS-System Disk from the CD drive.
- 6. Press the power on/off (0) switch to power off the system.

The system screen goes dark and powers off. Wait 20 seconds before powering on the system.

7. Press the power on/off (b) switch to power on the system.

The system will boot up in approximately three minutes. If an "Extended Post" message displays, then select **OK** to dismiss the dialog box.

#### [1] Instructions for Use

Supplying Power to 4-13 the System

- 8. To confirm the software installation:
  - a. Press **F6** to display the **Preset Main Menu**.
  - b. Select Service.
  - c. Confirm that the version of the system host software listed in the Product SW version matches the version of software from the OS-System Disk.
  - d. Select Cancel to exit the service login window.
- 9. To change the system language:
  - a. Select **System/Language** on the left of the screen.

**Note**: **System/Language** may appear on the second page of the **Presets Main Menu**. To see the second page of the menu, roll the trackball to the down arrow at the bottom of the menu and press the **SET** key on the control panel.

b. Select the required language and then select the **Change Language** button.

The system screen goes dark and powers off. Wait 20 seconds before powering on the system.

- c. Press the power on/off ( $\circlearrowleft$ ) switch to power on the system.
- 10. Reinstall the key disk options.

# **Software-Based Option Installation**

You can install or uninstall a software-based option on the ultrasound system using a key disk (USB memory stick). One key disk is required for one option per system. You cannot concurrently install a key disk option on multiple systems. If subsequently uninstalled, the option key disk can be installed on a different SONOLINE G20 ultrasound system.

Observe the following precautions when using a key disk:

- Do not power on the ultrasound system with a key disk inserted in a USB port.
- Insert only one key disk at a time.
- Do not remove the key disk during option installation or uninstallation.

#### To install a software-based option:

- 1. Insert the media containing the option into one of the USB ports on the input/output panel.
- 2. Press the **F6** key on the keyboard.
  - The system displays the **Preset Main Menu**.
- Roll the trackball to **Installation from Key Disk** and then press the SET key.
- 4. Roll the trackball to the **Install** button and then press the **SET** key. The system displays a confirmation dialog box.
- 5. Roll the trackball to the **OK** button and then press the **SET** key.
  - The system displays a message box as the key disk flashes while the option is installed. When the installation is complete, the system displays a new message box.
- 6. Roll the trackball to the **OK** button and then press the **SET** key. The option is listed on the Installed Option screen.
- 7. Remove the key disk.

## To uninstall a software-based option:

- 1. Insert the source media for the option into one of the USB ports on the input/output panel.
- 2. Press the **F6** key on the keyboard.

The system displays the **Preset Main Menu**.

- 3. Roll the trackball to **Installation from Key Disk** and then press the **SET** key.
- 4. Roll the trackball to the **Uninstall** button and then press the **SET** key.

The sytem verifies that the inserted source media matches an installed option and then displays a confirmation box.

5. Roll the trackball to the **OK** button and then press the **SET** key.

The system displays a message box as the key disk flashes while the option is uninstalled. When the process in complete, the system displays a new message box.

- 6. Roll the trackball to the **OK** button and then press the **SET** key. The option is no longer listed on the Installed Option screen.
- 7. Remove the key disk.

# 5 Beginning an Examination

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# **Entering Patient Data**

Before beginning a patient examination, you can use the keyboard to enter general patient information into the **Patient Data** form.

- You can retrieve previously saved patient information from a compact disk (CD).
- You can also automatically register a new patient by pressing one of the documentation controls configured for disk storage when no patient is registered. The system opens a new study, identifying the Patient Name as an asterisk (\*) and the Patient ID as the opening date and time. You can then change the patient information for the current study while the study remains open.
- You can automatically register a new patient by using the Worklist search function.

#### To enter new patient information:

- 1. Press the **F1** function key located on the keyboard.
  - The system displays the **New Patient Data** form with a text entry cursor positioned in the **Last Name** field.

**Note:** You can also review and edit an existing form by pressing the **F3 (PATIENT DATA)** key.

- 2. Enter the patient information using the instructions on the following pages.
- 3. Select **OK** at the bottom of the form to confirm your entries or select **Cancel** to discard your entries.
  - To confirm your entries, roll the trackball to the **OK** button and then press the **SET** key to enter the patient information.
    - The system displays the image screen with the new patient information.
  - To exit the form without saving the entries, select **Cancel** at the bottom of the form.

The system redisplays the image screen with the previous patient's information and discards the entries on the new patient data form.

#### [1] Instructions for Use

Searching the	
Worklist	5-10
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Hospital Name	Ch 4

#### **System Reference**

Selecting Images and Studies Ch 4

# **Using the Patient Data Form**

The **Patient Data** form contains general and exam-specific information. A calendar tool is available for entering date-dependent information for OB exams.

To:	Perform this action:
Move the text cursor to the beginning position of the next entry field	Press the <b>TAB</b> key on the keyboard. You can also roll the trackball to the next field and then press the <b>SET</b> key on the control panel.
Delete characters	Press the <b>BACKSPACE</b> key on the keyboard.
Select a button or object on the form	Roll the trackball to the button or object and then press the <b>SET</b> key.
Save the new patient data, exit viewing/editing of the patient form, and redisplay the image screen	Roll the trackball to the <b>OK</b> button and then press the <b>SET</b> key or press the <b>RETURN</b> key on the keyboard.
Exit viewing/editing of the patient form, and redisplay the image screen without saving the new patient data	Roll the trackball to the <b>Cancel</b> button and then press the <b>SET</b> key.

## **Calendar Tool**

You can display a calendar tool in the Patient Data form for use with OB exams.



Example of Calendar Tool.

#### To use the calendar tool:

- 1. Roll the trackball to select the down arrow (▼) on a date field of the patient data form and press the **SET** key to access the calendar.
  - If a date has not been entered in the **LMP** field, the calendar automatically displays a date 60 days before the examination date. To confirm this date, select the **OK** button. To select another date, scroll through the months of the calendar.
- 2. To scroll through the months of the calendar, select either the back arrow (◄) or the forward arrow (►).
- Roll the trackball pointer to a date and then press the SET key.
   The system exits the calendar tool and places the selected date in the Patient Data form.
- 4. To exit the calendar without saving changes, select the **Cancel** button below the calendar.

# **General and Exam-Specific Clinical Data**

The Patient Data form contains a Physical/Clinical History section. This section contains general data entry fields for all exam types and specific fields for the following exam types:

- OB, Early OB, GYN, and EM1
- Cardiac
- Urology

# **General Information ■ All Exam Types**

The system transfers patient information to the patient report for exam types with a report. Use the system presets to select the measurement convention for the height and weight fields and to include an operator ID and the referring physician's name in a report.

#### **System Reference**

System Presets Ch 3



#### F6

## General

▶ Date Format

► Height and Weight Format



### F6

#### M&R

► Measurement and Report Preset

▶ ▶ Display Item

▶ Display Configuration

General

► Height and Weight Format

In this field:	Enter	
Last Name	Patient's last name.	
First Name	Patient's first name.	
MI	Patient's middle initial.	
Accession Number	Identification code indicating the sequence of the current study as related to other studies for this patient. Used for billing purposes. Typically generated by a HIS/RIS (Worklist) server.	
ID	Identification code for the patient.	
DOB	Patient date of birth using the format selected in system presets.	
	The system automatically calculates the patient age and displays the value in the <b>AGE</b> field.	
Sex	Patient sex.	
Referring MD	Name of the referring physician.	
Physician ID	Identification of the physician.	
Height	Patient height using the convention selected in the system presets.	
Weight	Patient weight using the convention selected in the system presets.	
Indication	Additional information.	

<sup>&</sup>lt;sup>1</sup> Requires software version 2.0 or higher

# Specific Patient Data Information • OB, Early OB, GYN, and EM

		Patient Data form:		
In this field:	Enter	OB, Early OB	GYN	EM <sup>1</sup>
LMP	Start date of the patient's Last Menstrual Period.	✓	✓	✓
	Use the keyboard or the calendar tool to enter this date. You can also allow the system to calculate the LMP based on the EDC. A calculated LMP displays two asterisks (**) next to the date.			
EDC	Estimated Date of Confinement.	✓		✓
	The system automatically calculates and displays the Estimated Date of Confinement based on the LMP or IVF date. (EDC = LMP + 280 days or IVF Date + 266 days.) Use the keyboard or the calendar tool to enter this date.			
IVF Date	Date of in-vitro fertilization.	✓		
	Use the keyboard or the calendar tool to enter this date. A calculated IVF displays two asterisks (**) next to the date.			
Clinical	Basis of Clinical Menstrual Age (CMA).	✓		✓
Menstrual Age Based On	The system calculates and displays the CMA based on the LMP or IVF date already entered. Press the <b>SET</b> key to specify whether the LMP date or IVF date will be used to determine the Clinical MA.			
Clinical MA	The system calculates and displays the Clinical Menstrual Age using the LMP or IVF. The Clinical MA displays in the patient report.	✓		✓
Gravida Para	Patient history of pregnancies, entered with the number keys.	✓	✓	✓
AB Ectopic	The entries in these fields are transferred to the Patient Report, but do not display on the image screen.			
MAFP	Maternal Alpha-Fetoprotein level, up to four numbers, including an optional decimal place.	✓		✓

<sup>&</sup>lt;sup>1</sup> Requires software version 2.0 or higher

# **Specific Patient Data Information • Cardiac**

		Patient Data form:
In this field:	Enter	Cardiac
SYS/DIA	Blood pressure, using the systole over diastole measurement in mmHg.	✓
BSA	Patient Body Surface Area in m <sup>2</sup> . The system automatically calculates the BSA (based on Height and Weight entries) and transfers the value to the patient report.	✓
	BSA is calculated with one of the following two formulas:	
	For height in centimeters and weight in kilograms:	
	BSA = $0.007184 \times (weight)^{0.425} \times (height)^{0.725}$	
	For height in feet/inches and weight in pounds:	
	BSA = $0.007184 \times (weight \times 0.454)^{0.425} \times (height \times 2.54)^{0.725}$	

# **Specific Patient Data Information • Urology**

		Patient Data form:
In this field	Enter	Urology
PSA	Prostate specific antigen level in ng/ml.	✓

# **Selecting a Scheduled Procedure**

(Requires the DICOM option and the DICOM Modality Worklist option)

You can select a scheduled procedure using the Worklist search method or the DIMAQ method.

**Note:** The DIMAQ method for selecting a scheduled procedure requires software version 2.0 or higher.

То	Use this method:
Register a new patient (automatically enter the patient data for a procedure into the <b>New Patient Data</b> form)	Worklist search
Select another procedure for the current study (different accession number)	Worklist search
Select another procedure for the current study (same accession number)	DIMAQ

# Searching the Worklist

You can use the Worklist search function to select a scheduled procedure for a new study. You can also use the Worklist search function to select a scheduled procedure for the current study (different accession number).

**Note:** If the Worklist server assigns the same accession number to procedures within a study, then use DIMAQ to select another procedure for the current study.

### To search the Worklist server and begin a scheduled procedure:

1. Press the **F1** function key located on the keyboard.

The system displays the **New Patient Data** form with a text entry cursor positioned in the **Last Name** field.

2. Enter patient information for the search and then select the **Worklist** button.

The system displays the **Worklist Search** screen, containing data entered on the **New Patient Data** form. If streamlined search is enabled, then the system begins searching procedures scheduled for the next 24 hours using data entered on the **New Patient Data** form.

**Note**: To avoid retrieving patient data when selecting a scheduled procedure for the currently registered patient, select **Use Cache** in the **Offline** field of the **Worklist Search** screen.

- 3. If streamlined search is not enabled, then enter additional search criteria (if required) and begin the search:
  - a. Enter additional search criteria using the keyboard.
    - To access the next field, press the TAB key on the keyboard.
    - To remove data from the selected field, select **Clear**.
  - b. Select **Search** to begin the search.

The system displays the search results at the top of the **Worklist Search** screen and activates the **Scheduled Procedures** field and the **Select** button.

- 4. To sort patient data:
  - Select a column heading to sort the files in ascending order by heading.
  - Select the column heading again to sort in descending order.

#### [1] Instructions for Use

Selecting a
Scheduled
Procedure Using
DIMAQ 5-12



#### \_\_\_\_

DICOM

► Worklist Server

► Streamlined Search

- 5. To begin a new study:
  - a. Select a study from the top of the Worklist Search screen.

**Note:** When the Worklist server assigns different accession numbers to procedures within a study, the system lists each procedure separately at the top of the **Worklist Search** screen.

b. Select (click) the **Select** button.

The system transfers the patient data into the **New Patient Data** form.

c. Use the keyboard to edit or enter data and then select  $\mathbf{OK}$  to begin the study.

**Note:** The following fields cannot be edited for patient data transferred from the Worklist server: **Patient Name, Patient ID, Accession #, DOB/Age, Sex**.

- 6. To begin another scheduled procedure for the current study (different accession number):
  - a. Select a study from the top of the Worklist Search screen.

**Note:** When the Worklist server assigns different accession numbers to procedures within a study, the system lists each procedure separately at the top of the **Worklist Search** screen.

- b. Select (click) the Select button.
- c. Select **OK** in the confirmation message to end the current procedure.
- d. Select either **Completed** or **Discontinued** in the confirmation message to indicate status of the ended procedure and to begin the selected procedure.

### Selecting a Scheduled Procedure Using DIMAQ

You can use DIMAQ to select a scheduled procedure for the current study (same accession number). Use DIMAQ if the Worklist server assigns the same accession number to procedures within a study (that is, if procedures are entered into the Worklist server using a billing model that is based on the Integrated Healthcare Enterprise [IHE] guidelines).

Note: If the Worklist server assigns different accession numbers to procedures within a study, then use the Worklist search feature to select another procedure for the current study.

### To select another procedure (same accession number) for the currently registered patient:

Note: You must configure and activate a DICOM configuration (alias) for the MPPS server before using the Worklist search feature to select procedures.

- 1. Press the **REVIEW** key on the control panel to display the Image screen.
- 2. Select the **Procedure Screen** button on the left of the screen to display the **Choose procedure** screen.

Note: This selection is available when a connected DICOM Worklist server contains multiple procedures (same accession number) for the current study.

3. Select the procedure from the **Scheduled Procedure(s)** drop-down list and then select the **Select** button on the right of the screen.

The system displays a confirmation message.

4. Select **OK** in the confirmation message to end the current procedure.

The system displays another confirmation message.

- 5. Select either **Completed** or **Discontinued** in the confirmation message to indicate status of the ended procedure and to begin the selected procedure.
- 6. Select the **Live Screen** button to display the image screen.

#### **System Reference**

DICOM Connectivity Option Ch 6

#### [1] Instructions for Use

Searching the Worklist 5-10

# Fields Displayed on the Worklist Search Screen

In this field:	Enter	
Scheduled Procedures	Lists available procedures for the selected study. Procedures are identified by study code and description.	
	For software versions 2.0 and higher: Procedures are also identified by modality ( <b>US</b> is ultrasound).	
Patient Name		
Last	Last name of patient.Use an asterisk (*) to indicate partially known values. For example, to search for the last name "Miller", you can enter "Mil*" or "*ler".	
First	First name of patient. Use an asterisk (*) to indicate partially known values. For example, to search for the first name "Christopher", you can enter "Chris*" or "*pher".	
Middle	Middle initial of patient.	
Patient ID	Identification code for the patient. Searching for the ID requires an exact match.	
Performing Physician <sup>1</sup>		
Last <sup>1</sup>	Last name of performing physician. Use an asterisk (*) to indicate partially known values. For example, to search for the last name "Miller", you can enter "Mil*" or "*ler".	
First <sup>1</sup>	First name of performing physician. Use an asterisk (*) to indicate partially known values. For example, to search for the first name "Christopher", you can enter "Chris*" or "*pher".	
Middle <sup>1</sup>	Middle initial of performing physician.	

-

<sup>&</sup>lt;sup>1</sup> Requires software version 2.0 or higher

In this field:	Enter	
Date	Dates for the search.	
Accession #	Accession #. Searching for the accession number requires an exact match.	
Requested Procedure ID	Requested procedure ID. Searching for the requested procedure ID requires an exact match.	
Scope	Select <b>US Only</b> to search for procedures scheduled on all ultrasound systems; select <b>This system only</b> to confine the search to procedures scheduled on this ultrasound system.	
Offline	Select the <b>Use Cache</b> check box to save results of the most recent Worklist search on the ultrasound system. When <b>Use Cache</b> is selected, fields and buttons within the <b>Search Criterion</b> section at the bottom of the <b>Worklist Search</b> screen are not available.	
	You are unable to enter search criteria or perform a search if <b>Use Cache</b> is selected.	
	Select the <b>Reset Cache</b> button to clear any existing Worklist search results already stored on the ultrasound system. The system then downloads the current Worklist search results onto the ultrasound system. When you select the <b>Reset Cache</b> button, the system selects the <b>Use Cache</b> checkbox automatically. You can then move the system to another location; the results of the search are available on the ultrasound system even when it is not connected to the network.	
	<b>Note:</b> Before performing another search, reconnect the system to the network and ensure that <b>Use Cache</b> is not selected.	

### Fields Displayed on the Choose Procedure Screen

(Requires software version 2.0 or higher)

The **Choose procedure** screen displays the selections in the **Worklist Search** screen.Only the **Scheduled Procedures** drop-down list is available.

Selection	Description
Scheduled Procedures	Lists available procedures for the selected study. Procedures are identified by modality, study code, and description. For modality, <b>US</b> is ultrasound.

# **Editing Patient Data**

You can edit entries on the **Patient Data** form at any time during the patient examination.

### To display the Patient Data form:

1. Press the **F3** function key on the keyboard.

The system displays the Patient Data form.

2. Use the keyboard to update your entries.

Changes to the **Patient Data** form are also updated on the image screen and in the report for exams with a patient report.

Changes to fields used in calculations cause the system to update previously measured results.

3. Roll the trackball to the **OK** button and then press the **SET** key to save the revisions to the patient information and redisplay the image screen. To restore the current **Patient Data** form and redisplay the image screen without saving the revisions, roll the trackball to the **Cancel** button and then press the **SET** key.

# **Changing the Exam Type**

You can change the exam type at any time by making a selection from the **Exam and QuickSet List**. System-defined exam types and user-defined QuickSets display on this list. A QuickSet is an optimized configuration of imaging parameter settings for a specific transducer, exam, and operating mode.

Use the system presets to select an exam or QuickSet to automatically activate when you power on the system.

# Accessing the Exam and QuickSet List

Use one of these methods to access the Exam and QuickSet List:

- Press the **F5** key on the keyboard.
- Roll the trackball to the EXAM button on the New Patient Data or Patient Data form and then press the SET key.

#### To select or change the exam type or QuickSet:

1. Access the **Exam and QuickSet List** by pressing the **F5** key on the keyboard.

The system displays a list of system-defined exam types and a list of QuickSets.

Note: If the transducer associated with a QuickSet is not connected to the system, the QuickSet is not selectable.

- 2. Roll the trackball to highlight the name of the required exam type or the QuickSet and then press the SET key. The system displays the name of the selected exam type or QuickSet in the upper left of the image screen.
- 3. To redisplay the image screen without selecting an exam type or QuickSet, select the Cancel button.

#### [2] Instructions for Use

Creating QuickSets

Ch A1



F6

Boot Up ► Boot Up Exam & QuickSet

# **Exam Type Abbreviations**

The system displays an abbreviation that indicates the active exam type in the upper left of the image screen. The system-defined exams are abbreviated as follows:

Abd AbdominalOB Obstetrics

■ Early OB Early Obstetrics

**Breast Breast Thyroid** Thyroid **Testicle** Testicle **GYN** Gynecology Ortho Orthopedics Cardiac Cardiac Urology Urology **Cranial** Cranial Rectal<sup>1</sup> Rectal

■ **EM**<sup>1</sup> Emergency Medicine

-

<sup>&</sup>lt;sup>1</sup> Requires software version 2.0 or higher

# **Activating a Transducer**

Although multiple transducers can be connected to the ultrasound system, only one transducer can be active.

Use the system presets to select the transducer port that will be active at system power-on.

### To activate a transducer connected to the system:

- Press the **TRANSDUCER** key located on the control panel.
   The name of the active transducer displays on the upper left of the screen.
- 2. To activate another transducer connected to the system, press the **TRANSDUCER** key again.

#### **System Reference**

System Presets

Ch 3



F6

Boot Up

► Transducer Port Active On Boot Up

# **Selecting an Operating Mode**

When powered on, the system automatically displays in 2D-mode. You can change modes by pressing the appropriate control or key located on the control panel. You can select A-mode and full-screen M-mode sweeps using the 2D-mode menu.

Use the system presets to display the 2D image simultaneously with the M-mode sweep when M-mode is selected. If you do not activate the bypass cursor display selection in the system presets, the system displays the 2D image with the cursor when M-mode is selected and you must select the control a second time to display the sweep.



F6

Default Settings ▶ Bypass M Cursor Display

Mode	Selection	
A-mode	Press the <b>2D</b> control on the control panel, press the <b>MENU</b> control on the control panel, and then select <b>A-mode</b> .	
2D-mode	Press the <b>2D</b> control on the control panel.	
Split (B+B) mode	Press the <b>SPLIT</b> key on the control panel.	
Dual-mode	Press the left or right <b>DUAL/SELECT</b> key on the control panel. A 2D image displays in the respective half of the image area. Press the other <b>DUAL/SELECT</b> key to display an image in the other half of the display area. The last <b>DUAL/SELECT</b> key pressed (left or right) establishes the active image. Press either key twice to display the image full-screen. Return to dual displays by pressing the key once again.	
4B-mode	Press the <b>4B</b> key on the control panel.	
2D/M-mode	Press the <b>M</b> control on the control panel two times while in 2D-mode.	
Split 2D/M-mode	Press the <b>SPLIT</b> key on the control panel and then press the <b>M</b> control.	
M-mode	Press the <b>M</b> control on the control panel two times while in 2D-mode, press the <b>MENU</b> control on the control panel, and then select <b>Full M</b> .	

# **Examination Completion**

# **Printing a Patient Report**

For exam types with a patient report, the system transfers labeled measurements and calculations from a Measurement Menu on the image screen to a report. You can print the report to an optionally installed video printer using the control panel, or you can transfer the report to the USB or RS-232C port by selecting the **Send Report** button on the report page.

#### **System Reference**

System Presets Printer Installation Ch 5

### Video Printer (On-board)

Use the system presets to assign a documentation control to the printing function.

### To print the report to an on-board video printer:

Press the documentation control (PRINT STORE, DIGITAL STORE 1, or **DIGITAL STORE 2**) on the control panel configured for the print function.

The system transfers the information displayed on-screen to the specified documentation device.

# F6

System Configuration

- ▶ Peripheral
- ▶ ► RS-232
- **▶** ► USB
- ► Customize Keys
- ▶ Storage

### **Peripheral Printer (Off-board)**

Use the system presets to assign functionality to the serial port or to a USB port as the destination for data sent through the system.

#### To send data to a USB port or the RS-232C port:

Roll the trackball to the **Send Report** button on the report and then press the **SET** key on the control panel.

The **Send Report** button is changed to the **Cancel** button.

#### To cancel the Send Report command:

- To interrupt immediately, roll the trackball to the Cancel button and then press the SET key.
- To stop after the current page, press the **ESCAPE** key.

# **Ending an Exam**

You can complete the patient examination from the DIMAQ-IP Image screen or Study screen.

### To access the DIMAQ-IP screens (Study screen and Image screen):

- 1. Press the **REVIEW** key on the control panel.
  - If a patient is currently registered, then the system displays the Image screen. If there is not a patient currently registered, then the system displays the Study screen.
- To display the Image screen (from the Study screen), select the Image Screen button on the left of the screen.
- 3. To display the Study screen (from the Image screen), select the **Study Screen** button on the left of the screen.

#### To complete the patient examination, choose one of the following:

- Select the Close Study button on the left of the Image screen.
- Select the Close or New button in the Study box on the right of the Study screen.
- Press the F1 key on the keyboard to begin a new examination and select the OK button to register the new patient.
- Shut down the ultrasound system.

You can change the **Patient Name** and/or **ID** without closing the current patient examination.

**Note:** If you select a previous study from the Study screen list when a study is current and has not been completed, the current study is not closed. You can select the current study again from the Study screen.

A current study is identifiable in the Study screen when the following two conditions are met:

- It has the most recent **Date/Time** stamp in the Study screen list.
- The Close button in the Study screen is available when this study is selected.

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### **Standard Features**

# **Operator Control Panel**

- Trackball
- Backlit controls and keys
- Task lighting for control panel
- Language-specific control panel overlays
- Alphanumeric keyboard with special function keys

# **Multi-Lingual System Operating Software**

- Windows®-based operating software
- Multi-language capability, selectable during software installation
- User-modifiable system presets, including libraries of annotations and pictograms
- QuickSet<sup>™</sup> feature for defining up to 32 sets of specific exam, transducer, and image parameter settings

# **Processing Power**

- DIMAQ-IP integrated workstation
- SynAps<sup>™</sup> synthetic aperture technology for improved image quality at depth
- Pathway for future performance expansion and technological innovations

### **High Resolution Monochrome Monitor**

- 30 cm (12-inch)
- High resolution, (non-interlaced) with 640 x 480 pixel display matrix
- Tilt of 15° up and 15° down
- Swivel of 270°
- Brightness, contrast, and degauss controls
- Energy savings compliant per VESA Display Power Management Signaling standard

### **Mobility**

- Mobile console with swivel wheels and brakes for transport
- Front steering handle for ease in mobility

# **Transducer Compatibility**

- 2.0 to 10.0 MHz imaging range capability
- Wideband MultiHertz<sup>™</sup> multiple frequency imaging
- System configurations:
  - Two standard array transducer ports
  - Two standard array transducer ports and one mechanical sector transducer port<sup>1</sup>
  - Two standard array transducer ports and one parking port for linear and curved array transducers
- Detachable transducer and gel holders
- Transducer cable management
- microCase<sup>™</sup> transducer miniaturization technology for increased user comfort and reduced fatigue
- Lightweight, ergonomic transducer design with SuppleFlex<sup>™</sup> cables

### **User-Accessible Connections**

- Compact disk CD-RW drive for use with the DIMAQ-IP integrated ultrasound workstation
- On-board location for one recording device (analog output)
- RS-232C port for data transfer to an off-board printer or personal computer (PC)
- USB port for off-board printer connectivity (2 ports) and for installation of software-based system options using a "key disk" (memory stick)
- Ethernet port
- User-programmable, dual-pedal footswitch (optional)

<sup>&</sup>lt;sup>1</sup> Requires software version 2.0 or higher

# **Operating Modes**

The following modes are available on the system:

# **Single Modes**

- 2D-mode, Dual mode, 4B-mode, and Split (B+B) mode in fundamental and harmonics
- M-mode
- A-mode

### **Mixed Modes**

2D/M-mode

# **Imaging Functions**

- 2D-mode and M-mode imaging with mixed modes for 2D/M and A-mode display
- 256 gray shade display with selectable gray maps (seven maps)
- Up to 22 choices for magnification in frozen or real-time imaging
- 20 mm to 240 mm depth of view display in 10 mm increments (transducer dependent)
- User-adjustable single, dual, and quadruple focusing
- CINE: Up to 255 gray scale frames
- Zoom
- ReadySet<sup>™</sup> on-screen workflow shortcuts for immediate access to the most frequently-used functions (user-programmable)
- QuickSet™ user-programmable system parameters for streamlining exam and workflow steps

# **Options**

- THI™ Tissue Harmonic Imaging Technology
  - Enhances visualization, particularly in difficult-to-image patients
  - Improves image contrast and spatial resolution; reduces noise
  - Ensemble Tissue Harmonic Imaging (THI) is available with the following transducers and THI frequencies:

C4-2¹: 5.0T, 5.6T
 C5-2: 5.0T, 5.6T
 L10-5: 10.0T

- TGO™ Tissue Grayscale Optimization Option
  - Provides "one-button" image optimization, by immediately adjusting imaging parameters to the tissue type being imaged
  - For use with every exam type and imaging frequency, including THI (when installed)
  - Available on all transducers
- DICOM 3.0 Connectivity Option
  - Software license for use of networking software
  - Provides digital image transfer using a DICOM network for both printing and storage. When the option is installed, the ultrasound system is a "DICOM Print Class User" (for printing to a networked DICOM printer) and a "DICOM Storage Class User" (for storage to a networked DICOM workstation and/or archive device).
- DICOM Modality Worklist Option (requires the DICOM Connectivity Option)
  - Software license for querying and directing the download of a patient work schedule from a HIS/RIS system (Hospital Information System/Radiology Information System) to the ultrasound system
  - Automatically populates the patient registration form with patient demographic information
- DICOM MPPS Option<sup>1</sup> (requires the DICOM Connectivity Option and DICOM Modality Worklist Option)
- Dual footswitch
- Monitor filter (for bright lighting conditions)
- Clip Store
- Brachytherapy Software option<sup>1</sup> (requires systems configured with a mechanical sector transducer port and the use of the Endo-P II transducer)

<sup>&</sup>lt;sup>1</sup> Requires software version 2.0 or higher

# Measurements, Calculations, and Reports

Two categories of measurements and calculations are available on the ultrasound system: general and exam-specific.

### **General Functions**

- 2D-mode and M-mode imaging have up to eight (8) distance sets of caliper measurements per image
- Area and circumference: up to eight Ellipse and Trace measurements per image
- Ratio Calculations

### **General 2D-Mode Measurements and Calculations**

- Angle
- Distance/Depth
- Circumference (using a Trace or Ellipse method)
- Area (using a Trace or Ellipse method)
- Volume (using a 2-Plane Volume or a 1-Plane Volume)
- Residual Volume and Thyroid Volume

### **General M-Mode Measurements and Calculations**

- Distance
- Time
- Heart Rate
- Slope
- Ratio Calculations

# **Exam-Specific Measurements and Calculations**

The measurement function is arranged by exam type and is available for use with all exam types.

### **Abdominal**

All general measurements and calculations

### **Breast**

All general measurements and calculations

### **Thyroid**

- All general measurements and calculations
- Thyroid volume

### **Testicle**

All general measurements and calculations

### Gynecology

- All general measurements and calculations
- Right and left follicle, uterus, and right and left ovary measurements
- Gynecology patient report

### **Urology**

- All general measurements and calculations
- Micturated volume
- Prostate dimensions
- Prostate and urology patient report

### Rectal<sup>1</sup>

- All general measurements and calculations
- Stepwise volume
- Incremental volume
- Rectal patient report

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<sup>&</sup>lt;sup>1</sup> Requires software version 2.0 or higher

- All general measurements and calculations
- Early OB and Standard OB parameter labels
- Early OB and Standard OB measurement labels
- Menstrual Age paramter labels
- Up to five user-defined Menstrual Age formulas or tables
- Up to five user-defined ratios of parameters
- Up to five user-defined Growth Analysis formulas or tables
- Up to five user-defined measurement labels are available in 2D-mode
- Calculations for parameters and estimated fetal weight (EFW)
- Calculations for both clinical and ultrasound menstrual age, and estimated date of confinement
- Two system-defined formulas for estimating fetal body weight: EFW1 and EFW2
- Up to five user-defined formulas for estimating fetal body weight
- Two formulas for composite ultrasound menstrual age calculation: Direct/Average, system-defined
- Early Obstetric patient report and Standard Obstetric patient report include a worksheet for viewing the progress of the report during the exam process and to edit the report, along with multiple fetus reporting capabilities
- Growth Analysis Graphs

#### [2] Instructions for Use

Obstetrics

Ch B2

### **Orthopedic**

- All general measurements and calculations
- Right and Left Hip Angle measurement
- Orthopedic report

### **Cranial**

• All general measurements and calculations

### **Cardiac**

- 2D-mode Trace, Distance, and Angle measurements
- Volume formulas for Left Ventricular function assessment (eight formulas)
- 2D-mode and M-mode calculations
- M-mode Slope, Heart Rate, Time, and Distance measurements
- Cardiac worksheet and patient report

# **Measurement Accuracy**

The following table describes the variability in accuracy for each parameter:

Parameter	Ranges	Accuracy
Image Depth Scale	20 to 240 mm	$< \pm 3\%$ of full scale
Image Time Scales	2, 4, 8, 16 sec.	< ± 5 ms
Two-dimensional Measurements		
<ul><li>Distance/Depth</li></ul>	up to 240 mm	$<\pm$ 3% or $<$ 1 mm, if below 33 mm
- Area	up to 999 cm <sup>2</sup>	$<\pm$ 6% or $<$ 66 mm <sup>2</sup> , if below 11 cm <sup>2</sup>
- Trace (Ellipse)	up to 999 cm <sup>2</sup>	$<\pm6\%$ or $<66$ mm <sup>2</sup> , if below 11 cm <sup>2</sup>
- Angle	0° to 180°	$<\pm$ 3% on ½ segment
- Ratio (A/B)		
Result B/A & (A-B)/A	up to 1.0	< ± 10% of A
Result A/B	1.0 to 99.9	< ± 10% of A
Time Motion (TM) Measurements	<b>;</b>	
- Depth	up to 240 mm	$<\pm3\%$ or $<0.5$ mm, if below 17 mm
- Time	up to 16 sec.	< ± 2%
- Heart Rate	15 to 999 bpm	< ± 5%
Volume Measurements		
- Volume (Area, Length, Diameter)	up to 999 cm <sup>3</sup>	$< \pm 9\%$ or $< 3.2$ cm <sup>3</sup> , if below 36 cm <sup>3</sup>
<ul> <li>Thyroid Volume</li> </ul>	up to 999 cm <sup>3</sup>	$< \pm 9\%$ or $< 3.2$ cm <sup>3</sup> , if below 36 cm <sup>3</sup>
– Urine Remainder	up to 999 ml	$< \pm 9\% \text{ or } < 3.2 \text{ cm}^3, \text{ if below } 36 \text{ cm}^3$

# **Image Display**

Video Standards:

Monitor. Monochrome, 30 cm (12-inch), high resolution, (non-interlaced) monitor

with 640 x 480 pixel display matrix

Gray Scale: 256 levels

Positive (black on white) or negative (white on black) Image polarity:

System displays current date and time above the imaging area. Date/Time display:

Clock freezes in frozen image.

Daylight saving time changes available in system presets.

3.5 MHz = 20 to 240 mmImage field size: 5.0 MHz = 20 to 240 mm(by frequency)

7.5 MHz = 20 to 140 mm10.0 MHz = 20 to 240 mm12.0 MHz = 20 to 240 mm

The depth is selectable in increments of 10 mm. Minimum and maximum depth values for each frequency are transducer dependent.

Left-to-right or right-to-left orientation for 2D, Split (B+B), Dual, and Image Orientation:

> 4B modes: 2D image in mixed 2D/M-mode. Active image indicator designates direction of scan. 90-degree rotation for 2D, Split (B+B),

Dual, and 4B modes; 2D image in 2D/M-mode.

Image can be offset vertically and horizontally Image Position:

2D steering for linear array transducers

Other Imaging Parameters:

Transmit power displayed in decibels (dB) or percentage (%)

Overall System Receiver Gain combined with DGC Gain totals 70 dB

Depth Gain Compensation (DGC) - Eight DGC slide controls for

DGC Gain

Pre-processing - Edge Enhancement in six steps; Image Persistence in

eight steps; Dynamic Range 35 to 70 dB in 1-dB steps.

Post-processing – Seven variable gray scale compression maps. Focusing – 1, 2, and 4 transmit focal zones for all electronic array transducers; number and position of focal zones are user-selectable

Image Screen

Display:

Millimeter (mm) scale marker with depth of display, focal zones: number and position, gray bar, trackball arbitration, active image

indicator, error and help messages.

Values for the following image parameters: 2D/M Gain, Dynamic

Range, Edge Enhancement, and Gain.

Active transducer and transmit frequency, exam type, active measurement method, Measurement Menu, Measured Results. Onscreen menu selections for mode-specific imaging and onscreen

menu selections for a feature.

ReadySet<sup>™</sup> on-screen workflow shortcuts.

Patient Data Form: Fields for identification of the patient and physician.

Text Annotation: Customize phrase libraries for patient reports and onscreen annotation.

You can directly enter text on the image screen using the keyboard.

Pictograms: Standard and exam-specific graphics representing anatomical

structures are user selectable. Transducer position and orientation are

also available for positioning on the pictograms.

# **System Requirements**

This section describes the power and environmental requirements for the ultrasound imaging system.

### **Power Supply Requirements**

MAINS Voltage	Range	Maximum Current	Frequency	
230V ~	196V~ to 264V~	1.6 amps	50/60 Hz	
115V ~	98V~ to 132V~	3.0 amps	50/60 Hz	
100V ~	90V~ to 110V~	3.5 amps	50/60 Hz	

# **Possible Combinations with Other Equipment**

Only the peripheral devices listed in the System Reference are approved for use with the ultrasound system. Any use of other devices with the system will be at the user's risk and may void the system warranty.

**System Reference** Accessories Ch 2 and Options

On-board peripheral devices must be installed by an authorized Siemens representative or approved third party.

MARNING: Accessory equipment connected to the analog and digital interfaces must be certified according to the respective EN and IEC standards (e.g., EN 60950 and IEC 60950 for data processing equipment and EN 60601-1 and IEC 60601-1 for medical equipment). Furthermore, all configurations shall comply with the system standards EN 60601-1-1 and IEC 60601-1-1. Anyone who connects additional equipment to the signal input or signal output ports configures a medical system and is therefore responsible that the system complies with the requirements of the system standards EN 60601-1-1 and IEC 60601-1-1. Siemens can only guarantee the performance and safety of the devices listed in the Accessories and Options chapter. If in doubt, consult Siemens service department or your local Siemens representative.

# Leakage Currents



MARNING: Connecting peripheral products and accessories from non-isolated sources may result in chassis leakage current exceeding safe levels.

# Audio, Video, and Data Transmission Connections Input and Output Signals

Input/Output	Connector
Composite Video	BNC-type (1 input, 2 output)
Y/C Video	S-terminal (1 input, 1 output)
USB	Series A type (2)
Ethernet	RJ45 (1)

Output	Connector
VGA	D-sub, 15-pin, female (1)
RS-232-C port for printer/VCR/PC communication	D-sub, 9-pin, female (1)
Remote printer connector	Mini-jack (stereo) (1)
B/W Video	BNC-type

# **Environmental Requirements**

EMC NOTE: Operating the ultrasound imaging system in close proximity to sources of strong electromagnetic fields, such as radio transmitter stations or similar installations may lead to interference visible on the monitor screen. However, the device has been designed and tested to withstand such interference and will not be permanently damaged.

	During Operation	Ambient (During Storage or Transportation)
Maximum Altitude:	Operation up to 3,000 meters (1060 hPa)	
Relative humidity:	20% to 80%, non-condensing	<= 95%
Temperature:		
System	+10°C to +40°C	-20°C to +60°C
Array Transducers		
C4-2	+10°C to +40°C	-10°C to +60°C
C5-2	+10°C to +40°C	-10°C to +60°C
C8-5	+10°C to +40°C	-10°C to +60°C
7.5L75S	+10°C to +40°C	-10°C to +60°C
L10-5	+10°C to +40°C	-10°C to +60°C
EC9-4	+10°C to +40°C	-40°C to +60°C
EV9-4	+10°C to +40°C	-10°C to +60°C
Mechanical Sector Transducers		
Endo-V II	+20°C to +40°C	-5°C to +50°C
Endo-P II	+15°C to +40°C	-10°C to +60°C

### **Protective Measures**

**Explosion protection:** This product is not designed for operation in areas subject to

explosion hazards.

# **Maximum Physical Dimensions**

Width: 464 mm Height: 1283 mm Depth: 675 mm

Weight: 60 kg, without documentation devices

Floor Clearance: 68 mm

# **System Classifications**

- Type of protection against electrical shock:
  - Class I
- Degree of protection against electrical shock:
  - Type B equipment
- Degree of protection against harmful ingress of water:
  - Ordinary equipment
- Degree of safety of application in the presence of a flammable anesthetic material with air or with oxygen or nitrous oxide:
  - Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- Mode of operation:
  - Continuous operation

# **Standards Compliance**

The SONOLINE G20 ultrasound imaging system is in compliance with the following standards, including all applicable amendments at the time of product release.

### **Quality Standards**

- FDA QSR 21 CFR Part 820
- ISO 9000:00
- ISO 13485
- EN 46001:96

### **Design Standards**

- UL 60601 2003
- CSA C22.2 No. 601.1
- EN 60601-1 and IEC 60601-1
- EN 60601-1-1 and IEC 60601-1-1
- EN 60601-1-2 and IEC 60601-1-2
- EN 60601-2-25 and IEC 60601-2-25
- EN 60601-2-37 and IEC 60601-2-37

### **Acoustic Output Standards**

- IEC 61157 (Declaration of Acoustic Power)
- AIUM/NEMA UD-2, 1998 Acoustic Output Measurement Standard for Diagnostic Ultrasound
- AIUM/NEMA UD-3, 1998 Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment

### **CE Declaration**

This product is provided with a CE marking in accordance with the regulations stated in Council Directive 93/42/EEC of June 14, 1993 concerning Medical Devices. Siemens Medical Solutions USA, Inc., is certified by Notified Body 0123 to Annex II.3 - Full Quality System.

Authorized EC Representative: Siemens Aktiengesellschaft **Medical Solutions** Henkestraße 127 D-91052 Erlangen Germany